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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1654; Project Identifier MCAI–2023–00920–T; Amendment 39–22520; AD 2023–16–01]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–12–20, which applied to certain Bombardier, Inc., Model CL–600–2B16 (604 Variant) airplanes. AD 2023–12–20 required replacing certain oxygen system hoses and prohibited installing affected oxygen hoses. Since the FAA issued AD 2023–12–20, the FAA has learned of an error in a required compliance time. This AD retains the requirements of AD 2023–12–20, with a revised compliance time for the replacement. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 23, 2023.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 23, 2023 (88 FR 46063, July 19, 2023).

The FAA must receive comments on this AD by September 21, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1654; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*
- You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2023–1654.

FOR FURTHER INFORMATION CONTACT: Elizabeth Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avsnyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–1654; Project Identifier MCAI–2023–00920–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Elizabeth Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avsnyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2023–12–20, Amendment 39–22479 (88 FR 46063, July 19, 2023) (AD 2023–12–20), for certain Bombardier, Inc., Model CL–600–2B16 (604 Variant) airplanes. AD 2023–12–20 was prompted by an MCAI originated by Transport Canada, which is the aviation authority for Canada. Transport Canada issued AD CF–2022–34, dated June 20, 2022 (Transport Canada AD CF–2022–34), to correct an unsafe condition.

AD 2023–12–20 required replacing oxygen system hoses having any part number in the O2C20T1 and O2C20T14 series and prohibited installing affected oxygen hoses. The FAA issued AD 2023–12–20 to address a leak in the oxygen system, which could result in failure to provide oxygen to passengers and crew and result in an oxygen-

enriched atmosphere creating a fire risk on the airplane.

Actions Since AD 2023–12–20 Was Issued

Since AD 2023–12–20 was issued, the FAA has learned that paragraph (g)(1) of AD 2023–12–20 contains an error in the compliance time for the replacement of the oxygen system hoses. As written, paragraph (g)(1) of AD 2023–12–20 requires compliance for the affected airplanes within 31 months, or no later than ''12 months after the completion of the interior modification specified in STC ST02355NY,'' whichever occurs first. The correct compliance time is within 31 months, or no later than ''12 months after the airplane reaches 6 years from the STC ST02355NY airplane's completion issuance (specific airplane's Modification Data Summary release date),'' whichever occurs first. Paragraph (g)(1) of this AD specifies the correct compliance time. The compliance time as written in AD 2023–12–20 could unnecessarily ground some airplanes. Correcting this error in this AD provides relief by extending the compliance time. There are no other changes in this AD.

While the two ADs are effective August 23, 2023, this AD supersedes AD 2023–12–20.

The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1654.

Related Service Information Under 1 CFR Part 51

This AD requires Bombardier Service Bulletins 605–35–006 and 650–35–002, both Revision 01, both dated January 28, 2022, which the Director of the Federal Register approved for incorporation by reference as of August 23, 2023 (88 FR 46063, July 19, 2023). This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD retains all of the requirements of AD 2023–12–20, with a revised compliance time for replacing the oxygen system hoses for certain airplanes.

Justification for Immediate Adoption and Determination of the Effective Date

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

The FAA has learned of an error in a compliance time that could unnecessarily ground some airplanes. Correcting this error provides relief by extending that compliance time, and is the only change in this AD. To address this issue in a timely manner, the FAA has determined that it is appropriate to require the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. Accordingly, notice and opportunity for prior public comment are unnecessary pursuant to 5 U.S.C. 553(b)(3)(B).

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

Regulatory Flexibility Act (RFA)

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

Costs of Compliance

The FAA estimates that this AD affects 42 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR RETAINED REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3 work-hours × $85 per hour = $255	$100	$355	$14,910

ESTIMATED COSTS FOR RETAINED OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × $85 per hour = $85	$0	$85

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

ESTIMATED COSTS OF RETAINED ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
3 work-hours × $85 per hour = $255	$100	$355

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2023–12–20, Amendment 39–22479 (88 FR 46063, July 19, 2023); and

■ b. Adding the following new airworthiness directive:

2023–16–01 Bombardier, Inc.: Amendment 39–22520; Docket No. FAA–2023–1654; Project Identifier MCAI–2023–00920–T.

(a) Effective Date

This airworthiness directive (AD) is effective August 23, 2023.

(b) Affected ADs

This AD replaces AD 2023–12–20, Amendment 39–22479 (88 FR 46063, July 19, 2023) (AD 2023–12–20).

(c) Applicability

This AD applies to Bombardier, Inc., Model C–600–2B16 (604 Variant) airplanes, certificated in any category, serial numbers 5701 through 5990 inclusive and 6050 through 6162 inclusive, with an interior modified in accordance with Supplemental Type Certificate (STC) ST02355NY.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Unsafe Condition

This AD was prompted by reports of oxygen leaks caused by cracked, brittle, or broken oxygen hoses that were found during scheduled maintenance tests of the airplane oxygen system. The FAA is issuing this AD to address a leak in the oxygen system. The unsafe condition, if not addressed, could result in failure to provide oxygen to passengers and crew and result in an oxygen-enriched atmosphere creating a fire risk on the airplane.

(f) Compliance

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

(g) Retained Replacement, With Revised Compliance Time in Paragraph (g)(1)

This paragraph restates the requirements of paragraph (g) of AD 2023–12–20, with a revised compliance time in paragraph (g)(1) of this AD. At the applicable compliance times specified in paragraphs (g)(1) and (2) of this AD: Replace oxygen system hoses having any part number in the O2C20T1 series, and, as applicable, the O2C20T14 series, in accordance with the Accomplishment Instructions of the applicable service information specified in figure 1 to paragraph (g) of this AD.

(1) For airplanes having, as of the effective date of this AD, 6 years or less from the completion of the interior modification specified in STC ST02355NY: Within 31 months after the effective date of this AD, or no later than 12 months after the airplane reaches 6 years from the STC ST02355NY airplane's completion issuance (specific airplane's Modification Data Summary release date), whichever occurs first.

(2) For airplanes having, as of the effective date of this AD, more than 6 years from the completion of the interior modification specified in STC T02355NY: Within 7 months after the effective date of this AD.

Figure 1 to paragraph (g) – *Service information*

Bombardier Airplane Model–	Bombardier Service Bulletin–
CL-600-2B16 (604 Variant) Challenger 605	605-35-006, Revision 01, dated January 28, 2022
CL-600-2B16 (604 Variant) Challenger 650	650-35-002, Revision 01, dated January 28, 2022

(h) Retained Optional Mitigation for Certain Airplanes, With No Changes

This paragraph restates the provisions of paragraph (h) of AD 2023–12–20, with no changes. For airplanes identified in Bombardier Service Bulletin 650–35–002, Revision 01, dated January 28, 2022, having, as of the effective date of this AD, less than 6 years from the completion of the interior modification specified in STC ST02355NY: In lieu of accomplishing the oxygen system hose replacement required by paragraph (g) of this AD, comply with all conditions specified in paragraphs (h)(1) through (3) of this AD.

(1) The passenger oxygen system is tested within 6 months after the effective date of this AD, and thereafter at intervals not to exceed 36 months, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 650–35–002, Revision 01, dated January 28, 2022.

(2) If, during a test specified in paragraph (h)(1) of this AD, any leak is found on any hose, all oxygen system hoses having a part number in the O2C20T1 series must be replaced before further flight in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 650–35–002, Revision 01, dated January 28, 2022. Doing this replacement terminates the tests specified in paragraph (h)(1) of this AD.

(3) Except as specified by paragraph (h)(2) of this AD, all oxygen system hoses having a part number in the O2C20T1 series must be replaced within 6 years from the completion of the interior modification specified in STC ST02355NY. Doing this replacement terminates the tests specified in paragraph (h)(1) of this AD.

(i) Retained Parts Installation Prohibition, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2023–12–20, with no changes. As of the effective date of this AD, no person may install any oxygen system hose having a part number in the O2C20T1 and O2C20T14 series on any airplane.

(j) Retained Credit for Previous Actions, With No Changes

This paragraph restates the provisions of paragraph (j) of AD 2023–12–20, with no changes.

(1) This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 605–35–006, dated August 23, 2021; or Bombardier Service Bulletin 650–35–002, dated August 23, 2021; as applicable.

(2) This paragraph provides credit for actions specified in paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 650–35–002, dated August 23, 2021.

(k) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (l)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email.

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

(ii) AMOCs approved for AD 2023–12–20 are approved as AMOCs for the corresponding provisions of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(l) Additional Information

(1) Refer to Transport Canada AD CF–2022–34, dated June 20, 2022, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2023–1654.

(2) For more information about this AD, contact Elizabeth Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(4) and (5) of this AD.

(m) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on August 23, 2023 (88 FR 46063, July 19, 2023).

(i) Bombardier Service Bulletin 605–35–006, Revision 01, dated January 28, 2022.

(ii) Bombardier Service Bulletin 650–35–002, Revision 01, dated January 28, 2022.

(4) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

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

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

Issued on July 31, 2023.

Victor Wicklund,

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

[FR Doc. 2023–16648 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0927; Project Identifier MCAI–2023–00013–T; Amendment 39–22461; AD 2023–12–03]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting an airworthiness directive (AD) that was published in the **Federal Register**. That AD applies to certain Airbus SAS Model A350–941 and –1041 airplanes. As published, a European Union Aviation Safety Agency (EASA) AD number specified in the regulatory text is incorrect. This document corrects that error. In all other respects, the original document remains the same.

DATES: This correction is effective August 7, 2023. The effective date of AD 2023–12–03 remains August 7, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 7, 2023 (88 FR 42598, July 3, 2023).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0927; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule; correction, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this IBR material on the EASA website at *ad.easa.europa.eu.*

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at regulations.gov under Docket No. FAA–2023–0927.

FOR FURTHER INFORMATION CONTACT: Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7317; email *dat.v.le@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

AD 2023–12–03, Amendment 39–22461 (88 FR 42598, July 3, 2023) (AD 2023–12–03), requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations for airplane structures and safe life limits. That AD applies to certain Airbus SAS Model A350–941 and –1041 airplanes.

Need for the Correction

As published, paragraph (i) in the regulatory text of AD 2023–12–03 is incorrect. Paragraph (i) of AD 2023–12–03 refers to ''EASA AD 2023–0017.'' The correct reference is ''EASA AD 2023–0004.''

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0004, dated January 6, 2023, describes new or more restrictive airworthiness limitations for airplane structures and safe life limits. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Correction of Publication

This document corrects an error and correctly adds the AD as an amendment to 14 CFR 39.13. Although no other part of the preamble or regulatory information has been corrected, the FAA is publishing the entire rule in the **Federal Register**.

The effective date of this AD remains August 7, 2023.

Since this action only corrects an EASA AD reference, it has no adverse economic impact and imposes no additional burden on any person. Therefore, the FAA has determined that notice and public procedures are unnecessary.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Corrected]

■ 2. The FAA corrects § 39.13 by correcting the airworthiness directive published at 88 FR 42598 (July 3, 2023) to read:

2023–12–03 Airbus SAS: Amendment 39–22461; Docket No. FAA–2023–0927; Project Identifier MCAI–2023–00013–T.

(a) Effective Date

This airworthiness directive (AD) is effective August 7, 2023.

(b) Affected ADs

This AD affects AD 2023–04–05, Amendment 39–22352 (88 FR 13668, March 6, 2023) (AD 2023–04–05).

(c) Applicability

This AD applies to Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 1, 2022.

(d) Subject

Air Transport Association (ATA) of America Code: 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0004, dated January 6, 2023 (EASA AD 2023–0004).

(h) Exceptions to EASA AD 2023–0004

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2023–0004.

(2) Paragraph (3) of EASA AD 2023–0004 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA 2023–0004 is on or before the applicable ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2023–0004, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraph (4) of EASA AD 2023–0004.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0004.

(i) Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2023–0004.

(j) Terminating Action for AD 2023–04–05

Accomplishing the actions required by this AD terminates the corresponding requirements of AD 2023–04–05, for the tasks identified in the service information referenced in EASA AD 2023–0004 only.

(k) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(l) Additional Information

For more information about this AD, contact Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7317; email *Dat.V.Le@faa.gov.*

(m) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on August 7, 2023 (88 FR 42598, July 3, 2023).

(i) European Union Aviation Safety Agency (EASA) AD 2023–0004, dated January 6, 2023.

(ii) [Reserved]

(4) For EASA AD 2023–0004, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on August 1, 2023.

Victor Wicklund,

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

[FR Doc. 2023–16884 Filed 8–3–23; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 555

Mali Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending and replacing the Mali Sanctions Regulations, published in abbreviated form on February 7, 2020, to further implement a July 26, 2019 Mali-related Executive order and provide a more comprehensive set of regulations, including additional interpretive and definitional guidance, general licenses, and other regulatory provisions.

DATES: This rule is effective August 7, 2023.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Background

On February 7, 2020, OFAC issued the Mali Sanctions Regulations, 31 CFR part 555 (85 FR 7223, February 7, 2020) (the ''Regulations''), to implement Executive Order (E.O.) 13882 of July 26, 2019, ''Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Mali'' (84 FR 37055, July 30, 2019), pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13882. The Regulations were initially issued in abbreviated form for the purpose of providing immediate guidance to the public. OFAC is revising the Regulations to further implement E.O. 13882. OFAC is amending and reissuing the Regulations as a more comprehensive set of regulations that includes additional interpretive guidance and definitions, general licenses, and other regulatory provisions that will provide further guidance to the public. Due to the number of regulatory sections being updated or added, OFAC is reissuing the Regulations in their entirety.

On July 26, 2019, the President, invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA) and the United Nations Participation Act (22 U.S.C. 287c) (UNPA), issued E.O. 13882. In E.O. 13882, the President determined that the situation in Mali, including repeated violations of ceasefire arrangements made pursuant to the 2015 Agreement on Peace and Reconciliation in Mali; the expansion of terrorist activities into southern and central Mali; the intensification of drug trafficking and trafficking in persons, human rights abuses, and hostage-taking; and the intensification of attacks against civilians, the Malian defense and security forces, the United Nations Multi-dimensional Integrated Stabilizations Mission in Mali (MINUSMA), and international security presences, constituted an unusual and extraordinary threat to the national security and foreign policy of the United States and declared a national emergency to deal with that threat.

Section 1 of E.O. 13882 blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of any person determined by the Secretary of the Treasury, in consultation with the Secretary of State to: (i) be responsible for or complicit in, or to have directly or indirectly engaged in, any of the following in or in relation to Mali: (A) actions or policies that threaten the peace, security, or stability of Mali; (B) actions or policies that undermine democratic processes or institutions in Mali; (C) a hostile act in violation of, or an act that obstructs, including by prolonged delay, or threatens the implementation of, the 2015 Agreement on Peace and Reconciliation in Mali; (D) planning, directing, sponsoring, or conducting attacks against local, regional, or state institutions, the Malian defense and security forces, any international security presences, MINUSMA peacekeepers, other United Nations or associated personnel, or any other peacekeeping operations; (E) obstructing the delivery or distribution of, or access to, humanitarian assistance; (F) planning, directing, or committing an act that violates international humanitarian law or that constitutes a serious human rights abuse or violation, including an act involving the targeting of civilians through the commission of an act of violence, abduction or enforced disappearance, forced displacement, or an attack on a school, hospital, religious site, or location where civilians are seeking refuge; (G) the use or recruitment of children by armed groups or armed forces in the context of the armed conflict in Mali; (H) the illicit production or trafficking of narcotics or their precursors originating or transiting through Mali; (I) trafficking in persons, smuggling in migrants, or trafficking or smuggling arms or illicitly acquired cultural property; or (J) any transaction or series of transactions involving bribery or other corruption, such as the misappropriation of Malian public assets or expropriation of private assets for personal gain or political purposes; (ii) have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, any person

whose property and interests in property are blocked pursuant to E.O. 13882; or (iii) be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to E.O. 13882. The blocked property and interests in property of the persons described above may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

In Section 3 of E.O. 13882, the President determined that the making of donations of the type of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)), by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13882 would seriously impair the President's ability to deal with the national emergency declared in E.O. 13882. The President therefore prohibited the donation of such items except to the extent provided by statutes, or in regulations, rulings, instructions, orders, directives, or licenses that may be issued pursuant to E.O. 13882.

Section 4 of E.O. 13882 provides that the prohibition on any transaction or dealing in blocked property or interests in property includes the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13882, and the receipt of any contribution or provision of funds, goods, or services from any such person.

Section 5 of E.O. 13882 prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in E.O. 13882, as well as any conspiracy formed to violate such prohibitions.

Section 8 of E.O. 13882 authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA and the UNPA as may be necessary to carry out the purposes of E.O. 13882. Section 8 of E.O. 13882 also provides that the Secretary of the Treasury may redelegate any of these functions within the Department of the Treasury. In furtherance of the purposes of E.O. 13882, OFAC is amending the Regulations.

The Regulations implement targeted sanctions that are directed at persons determined to meet the criteria set forth in § 555.201 of the Regulations, as well as sanctions that may be set forth in any future Executive orders issued pursuant to the national emergency declared in E.O. 13882. The sanctions in E.O. 13882 do not generally prohibit trade or the provision of banking or other financial services to the country of Mali. Instead, the sanctions in E.O. 13882 apply where the transaction or service in question involves property or interests in property that are blocked pursuant to these sanctions.

Subpart A of the Regulations clarifies the relation of this part to other laws and regulations. Subpart B of the Regulations implements the prohibitions contained in sections 1, 4, and 5 of E.O. 13882, as well as the prohibitions contained in any further Executive orders issued pursuant to the national emergency declared in E.O. 13882. *See, e.g.,* §§ 555.201 and 555.205. Persons designated by or under the authority of the Secretary of the Treasury pursuant to E.O. 13882, or otherwise blocked pursuant to E.O. 13882, as well as persons who are blocked pursuant to any further Executive orders issued pursuant to the national emergency declared in E.O. 13882, are referred to throughout the Regulations as ''persons whose property and interests in property are blocked pursuant to § 555.201.'' The names of persons designated or identified as blocked pursuant to E.O. 13882, or any further Executive orders issued pursuant to the national emergency declared therein, are published on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List), which is accessible via OFAC's website. Those names also are published in the **Federal Register** as they are added to the SDN List.

Sections 555.202 and 555.203 of subpart B detail the effect of transfers of blocked property in violation of the Regulations and set forth the requirement to hold blocked funds, such as currency, bank deposits, or liquidated financial obligations, in interest-bearing blocked accounts. Section 555.204 of subpart B provides that all expenses incident to the maintenance of blocked tangible property shall be the responsibility of the owners and operators of such property, and that such expenses shall not be met from blocked funds, unless otherwise authorized. The section further provides that blocked property may, in OFAC's discretion, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

Section 555.205 of subpart B prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in § 555.201 of the Regulations, and any conspiracy formed to violate such prohibitions.

Section 555.206 of subpart B details transactions that are exempt from the prohibitions of the Regulations pursuant to section 203(b) of IEEPA (50 U.S.C. 1702(b)), but states that such exemptions do not apply for transactions involving persons blocked pursuant to the UNPA (22 U.S.C. 287c(b)).

In subpart C of the Regulations, new definitions are being added to other key terms used throughout the Regulations. Because these new definitions were inserted in alphabetical order, the definitions that were in the prior abbreviated set of regulations have been renumbered. Similarly, in subpart D, which contains interpretive sections regarding the Regulations, certain provisions have been renumbered and others added to those in the prior abbreviated set of regulations. Section 555.411 of subpart D explains that the property and interests in property of an entity are blocked if the entity is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked, whether or not the entity itself is incorporated into OFAC's SDN List.

Transactions otherwise prohibited by the Regulations but found to be consistent with U.S. policy may be authorized by one of the general licenses contained in subpart E of the Regulations or by a specific license issued pursuant to the procedures described in subpart E of 31 CFR part 501. In subpart E of the Regulations, OFAC is adding new § 555.506, which authorizes the investment and reinvestment of certain funds. OFAC is redesignating the general licenses at §§ 555.506 through 555.512 as §§ 555.507 through 555.513. General licenses and statements of licensing policy relating to this part also may be available through the Mali sanctions page on OFAC's website: *https://ofac.treasury.gov.*

Subpart F of the Regulations refers to subpart C of part 501 for recordkeeping and reporting requirements. Subpart G of the Regulations describes the civil and criminal penalties applicable to violations of the Regulations, as well as the procedures governing the potential imposition of a civil monetary penalty or issuance of a Finding of Violation. Subpart G also refers to appendix A of part 501 for a more complete description of these procedures.

Subpart H of the Regulations refers to subpart E of part 501 for applicable provisions relating to administrative procedures and contains a delegation of certain authorities of the Secretary of the Treasury. Subpart I of the Regulations sets forth a Paperwork Reduction Act notice.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of E.O. 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), as amended, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Part 555

Administrative practice and procedure, Banks, Banking, Blocking of assets, Credit, Foreign trade, Mali, Penalties, Reporting and recordkeeping requirements, Sanctions, Securities, Services.

For the reasons set forth in the preamble, OFAC revises 31 CFR part 555 to read as follows:

PART 555—MALI SANCTIONS REGULATIONS

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Sec.
555.101 Relation of this part to other laws and regulations.

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555.601 Records and reports.

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555.701 Penalties.
555.702 Pre-Penalty Notice; settlement.
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555.801 Procedures.
555.802 Delegation of certain authorities of the Secretary of the Treasury.

Subpart I—Paperwork Reduction Act

555.901 Paperwork Reduction Act notice.

Authority: 3 U.S.C. 301; 22 U.S.C. 287c; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13882, 84 FR 37055, 3 CFR, 2019 Comp., p. 346.

Subpart A—Relation of This Part to Other Laws and Regulations

§ 555.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and license application and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

Subpart B—Prohibitions

§ 555.201 Prohibited transactions.

(a) *E.O. 13882.* All property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(1) Any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) To be responsible for or complicit in, or to have directly or indirectly engaged in, any of the following in or in relation to Mali:

(A) Actions or policies that threaten the peace, security, or stability of Mali;

(B) Actions or policies that undermine democratic processes or institutions in Mali;

(C) A hostile act in violation of, or an act that obstructs, including by prolonged delay, or threatens the implementation of, the 2015 Agreement on Peace and Reconciliation in Mali;

(D) Planning, directing, sponsoring, or conducting attacks against local, regional, or state institutions, the Malian defense and security forces, any international security presences, the United Nations Multi-dimensional Integrated Stabilizations Mission in Mali peacekeepers, other United Nations or associated personnel, or any other peacekeeping operations;

(E) Obstructing the delivery or distribution of, or access to, humanitarian assistance;

(F) Planning, directing, or committing an act that violates international humanitarian law or that constitutes a serious human rights abuse or violation, including an act involving the targeting of civilians through the commission of an act of violence, abduction or enforced disappearance, forced displacement, or an attack on a school, hospital, religious site, or location where civilians are seeking refuge;

(G) The use or recruitment of children by armed groups or armed forces in the context of the armed conflict in Mali;

(H) The illicit production or trafficking of narcotics or their precursors originating or transiting through Mali;

(I) Trafficking in persons, smuggling migrants, or trafficking or smuggling arms or illicitly acquired cultural property; or

(J) Any transaction or series of transactions involving bribery or other corruption, such as the misappropriation of Malian public assets or expropriation of private assets for personal gain or political purposes;

(ii) To have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, any person whose property and interests in property are blocked pursuant to this paragraph (a); or

(iii) To be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this paragraph (a).

(b) The prohibitions in paragraph (a) of this section include prohibitions on the following transactions:

(1) The making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to paragraph (a) of this section; and

(2) The receipt of any contribution or provision of funds, goods, or services from any person whose property and interests in property are blocked pursuant to paragraph (a) of this section.

(c) Unless authorized by this part or by a specific license expressly referring to this part, any dealing in securities (or evidence thereof) held within the possession or control of a U.S. person and either registered or inscribed in the name of, or known to be held for the benefit of, or issued by, any person whose property and interests in property are blocked pursuant to this section is prohibited. This prohibition includes the transfer (including the transfer on the books of any issuer or agent thereof), disposition, transportation, importation, exportation, or withdrawal of, or the endorsement or guaranty of signatures on, any securities on or after the effective date. This prohibition applies irrespective of the fact that at any time (whether prior to, on, or subsequent to the effective date) the registered or inscribed owner of any such securities may have or might appear to have assigned, transferred, or otherwise disposed of the securities.

(d) The prohibitions of this section apply except to the extent provided by statutes, or in regulations, rulings, instructions, orders, directives, or licenses that may be issued pursuant to this part, and notwithstanding any contract entered into or any license or permit granted prior to the effective date.

(e) All transactions prohibited pursuant to any Executive order issued after July 30, 2019 pursuant to the national emergency declared in E.O. 13882 of July 30, 2019 are prohibited pursuant to this part.

Note 1 to § 555.201. The names of persons designated or identified as blocked pursuant to E.O. 13882, or any further Executive orders issued pursuant to the national emergency declared therein, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) using the following identifiers: for E.O. 13882: ''MALI–EO13882''; and for any further Executive orders issued pursuant to the national emergency declared in E.O. 13882: using the identifier formulation ''MALI–E.O.[E.O. number pursuant to which the person's property and interests in property are blocked]].'' The SDN List is accessible through the following page on OFAC's website: *www.treas.gov/sdn.* Additional information pertaining to the SDN List can be found in appendix A to this chapter. *See* § 555.411 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 555.201. The International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to this section also are published in the **Federal Register** and incorporated into the SDN List using the following identifiers: for E.O. 13882 ''[BPI–MALI–EO13882]''; and for any further Executive orders issued pursuant to the national emergency declared in E.O. 13882: ''[BPI–MALI–E.O.[E.O. number pursuant to which the person's property and interests in property are blocked pending investigation]].''

Note 3 to § 555.201. Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, or administrative reconsideration of their status as persons whose property and interests in property are blocked pursuant to this section.

§ 555.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, ruling, instruction, order, directive, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 555.201, is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or interest in property.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 555.201, unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, a license or other authorization issued by OFAC before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it would be valid or enforceable but for

the provisions of this part and any regulation, ruling, instruction, order, directive, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of OFAC each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with OFAC a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, order, directive, license, or other authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by OFAC; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

(e) The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (2) of this section have been satisfied.

(f) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property or interest in property blocked pursuant to § 555.201.

§ 555.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraph (e) or (f) of this section, or as otherwise directed or authorized by OFAC, any U.S. person holding blocked funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 555.201 shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For the purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For the purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For the purposes of this section, if interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 555.201 may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraph (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 555.201 may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

(g) This section does not create an affirmative obligation for the holder of blocked tangible property, such as real or personal property, or of other blocked property, such as debt or equity securities, to sell or liquidate such property. However, OFAC may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(h) Funds blocked pursuant to § 555.201 may not be held, invested, or reinvested in a manner that provides financial or economic benefit or access to any person whose property and interests in property are blocked pursuant to § 555.201, nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

§ 555.204 Expenses of maintaining blocked tangible property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted prior to the effective date, all expenses incident to the maintenance of tangible property blocked pursuant to § 555.201 shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 555.201 may, in the discretion of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

§ 555.205 Evasions; attempts; causing violations; conspiracies.

(a) Any transaction on or after the effective date that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this part is prohibited.

(b) Any conspiracy formed to violate the prohibitions set forth in this part is prohibited.

§ 555.206 Exempt transactions.

(a) *United Nations Participation Act.* The exemptions described in this section do not apply to transactions involving property or interests in property of persons whose property and interests in property are blocked pursuant to the authority of the United Nations Participation Act, as amended (22 U.S.C. 287c) (UNPA).

Note 1 to paragraph (a). Persons whose property and interests in property are blocked pursuant to the authority of the UNPA include those listed on *both* OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) and the Consolidated United Nations Security Council Sanctions List (UN List) (*see https://www.un.org*), as well as persons listed on the SDN List for being owned or controlled by, or acting for or on behalf of, persons listed on *both* the SDN List and the UN List.

(b) *International Emergency Economic Powers Act.* The prohibitions contained in this part do not apply to any transactions that are exempt pursuant to section 203(b) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)).

Subpart C—General Definitions

§ 555.300 Applicability of definitions.

The definitions in this subpart apply throughout the entire part.

§ 555.301 Blocked account; blocked property.

The terms *blocked account* and *blocked property* mean any account or property subject to the prohibitions in § 555.201 held in the name of a person whose property and interests in property are blocked pursuant to § 555.201, or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to a license or other authorization from OFAC expressly authorizing such action.

Note 1 to § 555.301. *See* § 555.411 concerning the blocked status of property and interests in property of an entity that is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked pursuant to § 555.201.

§ 555.302 Effective date.

(a) The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part, and, with respect to a person whose property and interests in property are blocked pursuant to § 555.201, the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

(b) For the purposes of this section, *constructive notice* is the date that a notice of the blocking of the relevant person's property and interests in property is published in the **Federal Register**.

§ 555.303 Entity.

The term *entity* means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

§ 555.304 Financial, material, or technological support.

The term *financial, material, or technological support* means any property, tangible or intangible, including currency, financial instruments, securities, or any other transmission of value; weapons or related materiel; chemical or biological agents; explosives; false documentation or identification; communications equipment; computers; electronic or other devices or equipment; technologies; lodging; safe houses; facilities; vehicles or other means of transportation; or goods.

''Technologies'' as used in this section means specific information necessary for the development, production, or use of a product, including related technical data such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals, or other recorded instructions.

§ 555.305 [Reserved]

§ 555.306 Interest.

Except as otherwise provided in this part, the term *interest,* when used with respect to property (*e.g.,* ''an interest in property''), means an interest of any nature whatsoever, direct or indirect.

§ 555.307 Licenses; general and specific.

(a) Except as otherwise provided in this part, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part or made available on OFAC's website: *https://ofac.treasury.gov.*

(c) The term *specific license* means any license or authorization issued pursuant to this part but not set forth in subpart E of this part or made available on OFAC's website: *https://ofac.treasury.gov.*

Note 1 to § 555.306. *See* § 501.801 of this chapter on licensing procedures.

§ 555.308 OFAC.

The term *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

§ 555.309 Person.

The term *person* means an individual or entity.

§ 555.310 Property; property interest.

The terms *property* and *property interest* include money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership, or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors' sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest or interests therein, present, future, or contingent.

§ 555.311 Transfer.

The term *transfer* means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property. Without limitation on the foregoing, it shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or credit; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, filing, or levy of or under any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.

§ 555.312 United States.

The term *United States* means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 555.313 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

§ 555.314 U.S. financial institution.

The term *U.S. financial institution* means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, purchasing or selling foreign exchange, securities, futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes depository institutions, banks, savings banks, money services businesses, operators of credit card systems, trust companies, insurance companies, securities brokers and dealers, futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, dealers in precious metals, stones, or jewels, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

Subpart D—Interpretations

§ 555.401 Reference to amended sections.

(a) Reference to any section in this part is a reference to the same as currently amended, unless the reference includes a specific date. *See* 44 U.S.C. 1510.

(b) Reference to any regulation, ruling, instruction, order, directive, or license issued pursuant to this part is a reference to the same as currently amended unless otherwise so specified.

§ 555.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any regulation, ruling, instruction, order, directive, or license issued by OFAC does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such regulation, ruling, instruction, order, directive, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 555.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person whose property and interests in property are blocked pursuant to § 555.201, such property shall no longer be deemed to be property blocked pursuant to § 555.201, unless there exists in the property another interest that is blocked pursuant to § 555.201, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 555.201, such property shall be deemed to be property in which such person has an interest and therefore blocked.

§ 555.404 Transactions ordinarily incident to a licensed transaction.

(a) Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(1) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 555.201; or

(2) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

(b) For example, a license authorizing a person to complete a securities sale involving Company A, whose property and interests in property are blocked pursuant to § 555.201, also authorizes other persons to engage in activities that are ordinarily incident and necessary to complete the sale, including transactions by the buyer, broker, transfer agents, and banks, provided that such other persons are not themselves persons whose property and interests in property are blocked pursuant to § 555.201.

§ 555.405 Provision and receipt of services.

(a) The prohibitions contained in § 555.201 apply to services performed in the United States or by U.S. persons, wherever located:

(1) On behalf of or for the benefit of any person whose property and interests in property are blocked pursuant to § 555.201; or

(2) With respect to property interests of any person whose property and interests in property are blocked pursuant to § 555.201.

(b) The prohibitions on transactions contained in § 555.201 apply to services received in the United States or by U.S. persons, wherever located, where the service is performed by, or at the direction of, a person whose property and interests in property are blocked pursuant to § 555.201.

(c) For example, U.S. persons may not, except as authorized by or pursuant to this part, provide legal, accounting, financial, brokering, freight forwarding, transportation, public relations, or other services to any person whose property and interests in property are blocked pursuant to § 555.201, or negotiate with or enter into contracts signed by a person whose property and interests in property are blocked pursuant to § 555.201.

Note 1 to § 555.405. *See* §§ 555.507 and 555.509 for general licenses authorizing the provision of certain legal and emergency medical services.

§ 555.406 Offshore transactions involving blocked property.

The prohibitions in § 555.201 on transactions or dealings involving blocked property, as defined in § 555.301, apply to transactions by any U.S. person in a location outside the United States.

§ 555.407 Payments from blocked accounts to satisfy obligations prohibited.

Pursuant to § 555.201, no debits may be made to a blocked account to pay obligations to U.S. persons or other persons, except as authorized by or pursuant to this part.

Note 1 to § 555.407. *See also* § 555.502(e), which provides that no license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

§ 555.408 Charitable contributions.

Unless specifically authorized by OFAC pursuant to this part, no charitable contribution of funds, goods, services, or technology, including contributions to relieve human suffering, such as food, clothing, or medicine, may be made by, to, or for the

benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 555.201. For the purposes of this part, a contribution is made by, to, or for the benefit of, or received from, a person whose property and interests in property are blocked pursuant to § 555.201 if made by, to, or in the name of, or received from or in the name of, such a person; if made by, to, or in the name of, or received from or in the name of, an entity or individual acting for or on behalf of, or owned or controlled by, such a person; or if made in an attempt to violate, to evade, or to avoid the bar on the provision of contributions by, to, or for the benefit of such a person, or the receipt of contributions from such a person.

§ 555.409 Credit extended and cards issued by financial institutions to a person whose property and interests in property are blocked.

The prohibition in § 555.201 on dealing in property subject to that section prohibits U.S. financial institutions from performing under any existing credit agreements, including charge cards, debit cards, or other credit facilities issued by a financial institution to a person whose property and interests in property are blocked pursuant to § 555.201.

§ 555.410 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. financial institution or other U.S. person, is a prohibited transfer under § 555.201 if effected after the effective date.

§ 555.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 555.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 555.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 555.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E, of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the Mali sanctions page on OFAC's website: *https://ofac.treasury.gov.*

§ 555.502 Effect of license or other authorization.

(a) No license or other authorization contained in this part, or otherwise issued by OFAC, authorizes or validates any transaction effected prior to the issuance of such license or other authorization, unless specifically provided in such license or authorization.

(b) No regulation, ruling, instruction, order, directive, or license authorizes any transaction prohibited under this part unless the regulation, ruling, instruction, order, directive, or license is issued by OFAC and specifically refers to this part. No regulation, ruling, instruction, order, directive, or license referring to this part shall be deemed to authorize any transaction prohibited by any other part of this chapter unless the regulation, ruling, instruction, order, directive, or license specifically refers to such part.

(c) Any regulation, ruling, instruction, order, directive, or license authorizing any transaction prohibited under this part has the effect of removing a prohibition contained in this part from the transaction, but only to the extent specifically stated by its terms. Unless the regulation, ruling, instruction, order, directive, or license otherwise specifies, such an authorization does not create any right, duty, obligation, claim, or interest in, or with respect to, any property that would not otherwise exist under ordinary principles of law.

(d) Nothing contained in this part shall be construed to supersede the requirements established under any other provision of law or to relieve a person from any requirement to obtain a license or other authorization from another department or agency of the U.S. government in compliance with applicable laws and regulations subject to the jurisdiction of that department or agency. For example, exports of goods, services, or technical data that are not prohibited by this part or that do not require a license by OFAC nevertheless may require authorization by the U.S. Department of Commerce, the U.S. Department of State, or other agencies of the U.S. government.

(e) No license or other authorization contained in or issued pursuant to this part authorizes transfers of or payments from blocked property or debits to blocked accounts unless the license or other authorization explicitly authorizes the transfer of or payment from blocked property or the debit to a blocked account.

(f) Any payment relating to a transaction authorized in or pursuant to this part that is routed through the U.S. financial system should reference the relevant OFAC general or specific license authorizing the payment to avoid the blocking or rejection of the transfer.

§ 555.503 Exclusion from licenses.

OFAC reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. OFAC also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

§ 555.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property and interests in property are blocked pursuant to § 555.201 has any interest that comes within the possession or control of a U.S. financial institution must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may be made only to another blocked account held in the same name.

Note 1 to § 555.504. *See* § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. *See also* § 555.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 555.505 Entries in certain accounts for normal service charges.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in

payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term *normal service charges* shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopies, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 555.506 Investment and reinvestment of certain funds.

Subject to the requirements of § 555.203, U.S. financial institutions are authorized to invest and reinvest assets blocked pursuant to § 555.201, subject to the following conditions:

(a) The assets representing such investments and reinvestments are credited to a blocked account or subaccount that is held in the same name at the same U.S. financial institution, or within the possession or control of a U.S. person, but funds shall not be transferred outside the United States for this purpose;

(b) The proceeds of such investments and reinvestments shall not be credited to a blocked account or subaccount under any name or designation that differs from the name or designation of the specific blocked account or subaccount in which such funds or securities were held; and

(c) No immediate financial or economic benefit accrues (*e.g.,* through pledging or other use) to a person whose property and interests in property are blocked pursuant to § 555.201.

§ 555.507 Provision of certain legal services.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 555.201 is authorized, provided that any receipt of payment of professional fees and reimbursement of incurred expenses must be authorized pursuant to § 555.508, which authorizes certain payments for legal services from funds originating outside the United States; via specific license; or otherwise pursuant to this part:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(4) Representation of persons before any U.S. federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 555.201, not otherwise authorized in this part, requires the issuance of a specific license.

(c) U.S. persons do not need to obtain specific authorization to provide related services, such as making filings and providing other administrative services, that are ordinarily incident to the provision of services authorized by paragraph (a) of this section. Additionally, U.S. persons who provide services authorized by paragraph (a) of this section do not need to obtain specific authorization to contract for related services that are ordinarily incident to the provision of those legal services, such as those provided by private investigators or expert witnesses, or to pay for such services. *See* § 555.404.

(d) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 555.201 is prohibited unless licensed pursuant to this part.

Note 1 to § 555.507. Pursuant to part 501, subpart E, of this chapter, U.S. persons seeking administrative reconsideration or judicial review of their designation or the blocking of their property and interests in property may apply for a specific license from OFAC to authorize the release of certain blocked funds for the payment of professional fees and reimbursement of incurred expenses for the provision of such legal services where alternative funding sources are not available.

§ 555.508 Payments for legal services from funds originating outside the United States.

(a) *Professional fees and incurred expenses.* (1) Receipt of payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 555.507(a) to or on behalf of any person whose property and interests in property are blocked pursuant to § 555.201, is authorized from funds originating outside the United States, provided that the funds do not originate from:

(i) A source within the United States;

(ii) Any source, wherever located, within the possession or control of a U.S. person; or

(iii) Any individual or entity, other than the person on whose behalf the legal services authorized pursuant to § 555.506(a) are to be provided, whose property and interests in property are blocked pursuant to any part of this chapter or any Executive order or statute.

(2) Nothing in this paragraph (a) authorizes payments for legal services using funds in which any other person whose property and interests in property are blocked pursuant to § 555.201, any other part of this chapter, or any Executive order or statute has an interest.

(b) *Reports.* (1) U.S. persons who receive payments pursuant to paragraph (a) of this section must submit annual reports no later than 30 days following the end of the calendar year during which the payments were received providing information on the funds received. Such reports shall specify:

(i) The individual or entity from whom the funds originated and the amount of funds received; and

(ii) If applicable:

(A) The names of any individuals or entities providing related services to the U.S. person receiving payment in connection with authorized legal services, such as private investigators or expert witnesses;

(B) A general description of the services provided; and

(C) The amount of funds paid in connection with such services.

(2) The reports, which must reference this section, are to be submitted to OFAC using one of the following methods:

(i) *Email (preferred method): OFACReport@treasury.gov;* or

(ii) *U.S. mail:* OFAC Regulations Reports, Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Freedman's Bank Building, Washington, DC 20220.

§ 555.509 Emergency medical services.

The provision and receipt of nonscheduled emergency medical services that are prohibited by this part are authorized.

§ 555.510 Official business of the United States government.

All transactions prohibited by this part that are for the conduct of the official business of the United States government by employees, grantees, or contractors thereof are authorized.

§ 555.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

§ 555.512 Certain transactions in support of nongovernmental organizations' activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 555.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

§ 555.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 555.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

Subpart F—Reports

§ 555.601 Records and reports.

For provisions relating to required records and reports, see part 501, subpart C, of this chapter. Recordkeeping and reporting requirements imposed by part 501 of this chapter with respect to the prohibitions contained in this part are considered requirements arising pursuant to this part.

Subpart G—Penalties and Findings of Violation

§ 555.701 Penalties.

(a) Section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705 (IEEPA) is applicable to

violations of the provisions of any regulation, ruling, instruction, order, directive, or license issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under IEEPA.

(1) A civil penalty not to exceed the amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any regulation, ruling, instruction, order, directive, license, or prohibition issued under IEEPA.

(2) IEEPA provides for a maximum civil penalty not to exceed the greater of $356,579 or an amount that is twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.

(3) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation of any regulation, ruling, instruction, order, directive, license, or prohibition may, upon conviction, be fined not more than $1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b)(1) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note).

(2) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(c) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the government of the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, imprisoned, or both.

(d) Section 5(b) of the United Nations Participation Act, as amended (22 U.S.C. 287c(b)) (UNPA), provides that any person who willfully violates or evades or attempts to violate or evade any order, rule, or regulation issued by the President pursuant to section 5(a) of the UNPA shall, upon conviction, be fined not more than $1,000,000 and, if a natural person, be imprisoned for not more than 20 years, or both.

(e) Violations involving transactions described at section 203(b)(1), (3), and (4) of IEEPA shall be subject only to the penalties set forth in paragraph (d) of this section.

(f) Violations of this part may also be subject to other applicable laws.

§ 555.702 Pre-Penalty Notice; settlement.

(a) *When required.* If OFAC has reason to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any regulation, ruling, instruction, order, directive, or license issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and determines that a civil monetary penalty is warranted, OFAC will issue a Pre-Penalty Notice informing the alleged violator of the agency's intent to impose a monetary penalty. A Pre-Penalty Notice shall be in writing. The Pre-Penalty Notice may be issued whether or not another agency has taken any action with respect to the matter. For a description of the contents of a Pre-Penalty Notice, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to respond to a Pre-Penalty Notice by making a written presentation to OFAC. For a description of the information that should be included in such a response, see appendix A to part 501 of this chapter.

(2) *Deadline for response.* A response to a Pre-Penalty Notice must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond.

(i) *Computation of time for response.* A response to a Pre-Penalty Notice must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the Pre-Penalty Notice was mailed or date the Pre-Penalty Notice was emailed. If the Pre-Penalty Notice was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to a Pre-Penalty Notice need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the Pre-Penalty Notice, and include the OFAC identification number listed on the Pre-Penalty Notice. The response must be sent to OFAC's Enforcement Division by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(c) *Settlement.* Settlement discussion may be initiated by OFAC, the alleged violator, or the alleged violator's authorized representative. For a description of practices with respect to settlement, see appendix A to part 501 of this chapter.

(d) *Guidelines.* Guidelines for the imposition or settlement of civil penalties by OFAC are contained in appendix A to part 501 of this chapter.

(e) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific allegations contained in the Pre-Penalty Notice must be preceded by a written letter of representation, unless the Pre-Penalty Notice was served upon the alleged violator in care of the representative.

§ 555.703 Penalty imposition.

If, after considering any written response to the Pre-Penalty Notice and any relevant facts, OFAC determines that there was a violation by the alleged violator named in the Pre-Penalty Notice and that a civil monetary penalty is appropriate, OFAC may issue a Penalty Notice to the violator containing a determination of the violation and the imposition of the monetary penalty. For additional details concerning issuance of a Penalty Notice, see appendix A to part 501 of this chapter. The issuance of the Penalty Notice shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

§ 555.704 Administrative collection; referral to United States Department of Justice.

In the event that the violator does not pay the penalty imposed pursuant to this part or make payment arrangements acceptable to OFAC, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate

action to recover the penalty in a civil suit in a federal district court.

§ 555.705 Findings of Violation.

(a) *When issued.* (1) OFAC may issue an initial Finding of Violation that identifies a violation if OFAC:

(i) Determines that there has occurred a violation of any provision of this part, or a violation of the provisions of any regulation, ruling, instruction, order, directive, or license issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*);

(ii) Considers it important to document the occurrence of a violation; and

(iii) Based on the Guidelines contained in appendix A to part 501 of this chapter, concludes that an administrative response is warranted but that a civil monetary penalty is not the most appropriate response.

(2) An initial Finding of Violation shall be in writing and may be issued whether or not another agency has taken any action with respect to the matter. For additional details concerning issuance of a Finding of Violation, see appendix A to part 501 of this chapter.

(b) *Response*—(1) *Right to respond.* An alleged violator has the right to contest an initial Finding of Violation by providing a written response to OFAC.

(2) *Deadline for response; default determination.* A response to an initial Finding of Violation must be made within 30 days as set forth in paragraphs (b)(2)(i) and (ii) of this section. The failure to submit a response within 30 days shall be deemed to be a waiver of the right to respond, and the initial Finding of Violation will become final and will constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(i) *Computation of time for response.* A response to an initial Finding of Violation must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier), or dated if sent by email, on or before the 30th day after the postmark date on the envelope in which the initial Finding of Violation was served or date the Finding of Violation was sent by email. If the initial Finding of Violation was personally delivered by a non-U.S. Postal Service agent authorized by OFAC, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(ii) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the discretion of OFAC, only upon specific request to OFAC.

(3) *Form and method of response.* A response to an initial Finding of Violation need not be in any particular form, but it must be typewritten and signed by the alleged violator or a representative thereof (electronic signature is acceptable), contain information sufficient to indicate that it is in response to the initial Finding of Violation, and include the OFAC identification number listed on the initial Finding of Violation. The response must be sent to OFAC's Enforcement Division by mail or courier or email and must be postmarked or date-stamped in accordance with paragraph (b)(2) of this section.

(4) *Information that should be included in response.* Any response should set forth in detail why the alleged violator either believes that a violation of the regulations did not occur and/or why a Finding of Violation is otherwise unwarranted under the circumstances, with reference to the General Factors Affecting Administrative Action set forth in the Guidelines contained in appendix A to part 501 of this chapter. The response should include all documentary or other evidence available to the alleged violator that supports the arguments set forth in the response. OFAC will consider all relevant materials submitted in the response.

(c) *Determination*—(1) *Determination that a Finding of Violation is warranted.* If, after considering the response, OFAC determines that a final Finding of Violation should be issued, OFAC will issue a final Finding of Violation that will inform the violator of its decision. A final Finding of Violation shall constitute final agency action. The violator has the right to seek judicial review of that final agency action in federal district court.

(2) *Determination that a Finding of Violation is not warranted.* If, after considering the response, OFAC determines a Finding of Violation is not warranted, then OFAC will inform the alleged violator of its decision not to issue a final Finding of Violation.

Note 1 to paragraph (c)(2). A determination by OFAC that a final Finding of Violation is not warranted does not preclude OFAC from pursuing other enforcement actions consistent with the Guidelines contained in appendix A to part 501 of this chapter.

(d) *Representation.* A representative of the alleged violator may act on behalf of the alleged violator, but any oral communication with OFAC prior to a written submission regarding the specific alleged violations contained in the initial Finding of Violation must be preceded by a written letter of representation, unless the initial Finding of Violation was served upon the alleged violator in care of the representative.

Subpart H—Procedures

§ 555.801 Procedures.

For license application procedures and procedures relating to amendments, modifications, or revocations of licenses; administrative decisions; rulemaking; and requests for documents pursuant to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a), see part 501, subpart E, of this chapter.

§ 555.802 Delegation of certain authorities of the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to E.O. 13882 of July 26, 2019, and any further Executive orders relating to the national emergency declared therein, may be taken by the Director of OFAC or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart I—Paperwork Reduction Act

§ 555.901 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures, and other procedures, see § 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

[FR Doc. 2023–16860 Filed 8–4–23; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 70 and 71.

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GLs 70 and 71, each of which was previously made available on OFAC's website.

DATES: GLs 70 and 71 were issued on July 20, 2023. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov/.*

Background

On July 20, 2023, OFAC issued GLs 70 and 71 to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587. GLs 70 and 71 each have an expiration date of October 18, 2023. Each GL was made available on OFAC's website (*https://ofac.treasury.gov/*) at the time of publication. The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 70

Authorizing the Wind Down of Transactions Involving Joint Stock Company Ural Mining and Metallurgical Company

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by Executive Order (E.O.) 14024 that are ordinarily incident and necessary to the wind down of any transaction involving Joint Stock Company Ural Mining and Metallurgical Company (UMMC), or any entity in which UMMC owns, directly or indirectly, a 50 percent or greater interest (collectively, the ''UMMC Entities''), are authorized through 12:01 a.m. eastern daylight time, October 18, 2023, provided that any payment to a UMMC Entity must be made into a blocked account in accordance with the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR).

(b) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation,* as amended; or

(3) Any transactions otherwise prohibited by the RuHSR, including transactions involving any person blocked pursuant to the RuHSR other than the UMMC Entities, unless separately authorized.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

Dated: July 20, 2023.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 71

Authorizing the Wind Down and Rejection of Transactions Involving Certain Entities Blocked on July 20, 2023

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by Executive Order (E.O.) 14024 that are ordinarily incident and necessary to the wind down of transactions involving one or more of the following blocked persons (collectively, the ''Blocked Entities'') are authorized through 12:01 a.m. eastern daylight time, October 18, 2023, provided that any payment to a Blocked Entity is made into a blocked account in accordance with the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR):

(1) Joint Stock Company Petersburg Social Commercial Bank;

(2) Joint Stock Company Locko Bank;

(3) Unistream Commercial Bank JSC;

(4) Joint Stock Company Commercial Bank Solidarnost;

(5) JSC Tinkoff Bank; or

(6) Any entity in which one or more of the above persons own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest.

(b) Except as provided in paragraph (c) of this general license, U.S. persons are authorized to reject, rather than block, and return to the originator or originating financial institution or their successor-in-interest, all transactions prohibited by E.O. 14024 that are ordinarily incident and necessary to the processing of funds involving one or more of the Blocked Entities as an originating, intermediary, or beneficiary financial institution, through 12:01 a.m. eastern daylight time, October 18, 2023.

(c) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation; or

(3) Any transactions otherwise prohibited by the RuHSR, including transactions involving any person blocked pursuant to the RuHSR other than the Blocked Entities described in paragraph (a) of this general license, unless separately authorized.

Bradley T. Smith,

Deputy Director, *Office of Foreign Assets Control.*

Dated: July 20, 2023.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2023–16731 Filed 8–4–23; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General License 40B.

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a web general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Venezuela Sanctions Regulations: GL 40B, which was previously made available on OFAC's website.

DATES: GL 40B was issued on July 10, 2023. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov/.*

Background

On July 10, 2023, OFAC issued GL 40B to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations, 31 CFR part 591. GL 40B was made available on OFAC's website (*https://ofac.treasury.gov/*) when it was issued. GL 40B was issued on July 10, 2023 and has an expiration date of July 10, 2024. The text of this GL is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 40B

Authorizing Certain Transactions Involving the Exportation or Reexportation of Liquefied Petroleum Gas to Venezuela

(a) Except as provided in paragraph (b) of this general license, all transactions related to the exportation or reexportation, directly or indirectly, of liquefied petroleum gas to Venezuela, involving the Government of Venezuela, Petróleos de Venezuela, S.A. (PdVSA), or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by E.O. 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized through 12:01 a.m. eastern daylight time, July 10, 2024.

(b) This general license does not authorize:

(1) Any payment-in-kind of petroleum or petroleum products; or

(2) Any transactions otherwise prohibited by the VSR, including transactions involving any blocked persons other than PdVSA, any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, or any Government of Venezuela person that is blocked solely pursuant to E.O. 13884.

(c) Effective July 10, 2023, General License No. 40A, dated July 7, 2022, is replaced and superseded in its entirety by this General License No. 40B.

Note to General License No. 40B: Nothing in this general license relieves any persons from compliance with the requirements of other Federal agencies, including the Department of Commerce's Bureau of Industry and Security.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

Dated: July 10, 2023.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2023–16732 Filed 8–4–23; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General Licenses 5K and 5L.

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued pursuant to the Venezuela Sanctions Regulations: GLs 5K and 5L, each of which was previously made available on OFAC's website.

DATES: GL 5K was issued on April 19, 2023. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov/.*

Background

On April 19, 2023, OFAC issued GL 5K to further delay the effectiveness of the authorization that was previously contained in GL 5. GL 5K was the twelfth iteration of GL 5 and superseded GL 5J (88 FR 6624). On July 19, 2023, OFAC issued GL 5L, which superseded GL 5K and further delayed the effectiveness of the authorization that was contained in GL 5. Both GLs were made available on OFAC's website (*https://ofac.treasury.gov*) when they were issued. The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 5K

Authorizing Certain Transactions Related to the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond on or After July 20, 2023

(a) Except as provided in paragraph (b) of this general license, on or after July 20, 2023, all transactions related to, the provision of financing for, and other dealings in the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond that would be prohibited by subsection l(a)(iii) of Executive Order (E.O.) 13835 of May 21, 2018, as amended by E.O. 13857 of January 25, 2019, and incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized.

(b) This general license does not authorize any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V.

(c) Effective April 19, 2023, General License No. 5J, dated January 17, 2023, is replaced and superseded in its entirety by this General License No. 5K.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: April 19, 2023.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 5L

Authorizing Certain Transactions Related to the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond on or After October 20, 2023

(a) Except as provided in paragraph (b) of this general license, on or after October 20, 2023, all transactions related to, the provision of financing for, and other dealings in the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond that would be prohibited by subsection l(a)(iii) of Executive Order (E.O.) 13835 of May 21, 2018, as amended by E.O. 13857 of January 25, 2019, and incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized.

(b) This general license does not authorize any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V.

(c) Effective July 19, 2023, General License No. 5K, dated April 19, 2023, is replaced and superseded in its entirety by this General License No. 5L.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

Dated: July 19, 2023.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2023–16729 Filed 8–4–23; 8:45 am]

BILLING CODE 4810–AL–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0576; FRL–11129–01–OCSPP]

Imazapic; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of imazapic in or on rice, bran and rice, grain. BASF requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 7, 2023. Objections and requests for hearings must be received on or before October 6, 2023, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0576, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2022–0576 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 6, 2023. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0576, by one of the following methods:

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 23, 2022 (87 FR 58047) (FRL–9410–05–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E9008) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709–3528. The petition requested that 40 CFR part 180.490 be amended by establishing tolerances for residues of the herbicide imazapic (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid), in or on rice, bran at 0.2 parts per million (ppm), and rice, grain at 0.05 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for imazapic

including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with imazapic follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Endpoints were previously selected for imazapic; however, the toxicological database was reevaluated as part of Registration Review. The no-observed adverse-effect level (NOAEL) and lowest-observed adverse-effect level (LOAEL) for the chronic oral toxicity study in dogs were updated to reflect current practices in hazard evaluation. The NOAEL is now 501 and 534 mg/kg/day in males and females, respectively. The LOAEL is now 1,141 and 1,092 in males and females, respectively, based on decreased body weight, increased incidence of salivation and emesis, changes in hematological parameters, red blood cell morphology findings, changes in clinical chemistry parameters, gross pathology in the bone marrow, and histopathological findings. Adverse effects in the database were only noted in two studies at doses that are not considered relevant for human health risk assessment (>500 mg/kg/day). Therefore, no endpoints were selected for imazapic and a quantitative assessment is not needed.

Specific information on the studies received and the nature of the adverse effects caused by imazapic as well as the NOAEL and LOAEL from the toxicity studies can be found at *https://www.regulations.gov* in document titled ''Imazapic Human Health Risk Assessment to Support the Establishment of a Tolerance without U.S. Registration in/on Rice'' (hereafter ''Imazapic Human Health Risk Assessment'' on pages 11–13 in docket ID number EPA–HQ–OPP–2022–0576).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

Since no effects were seen in any guideline toxicity studies at doses relevant for human health risk assessment, no toxicological PODs were selected for imazapic.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to imazapic, EPA considered exposure under the petitioned-for tolerances as well as all existing imazapic tolerances in 40 CFR 180.490. There is likely to be dietary exposure to imazapic from its use as a pesticide on imported and domestic food. Should exposure occur, however, minimal to no risk is expected for the general U.S. population, including infants and children, due to the low toxicity of imazapic.

2. *Dietary exposure from drinking water.* While there is no additional exposures expected from imazapic tolerances for rice because it is for import only, there is likely to be dietary exposure to imazapic in drinking water from its registered uses as a pesticide on domestic crops. Should exposure occur, however, minimal to no risk is expected for the general U.S. population, including infants and children, due to the low toxicity of imazapic.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Imazapic is registered for domestic uses that could result in residential exposure, including residential spot-treatment for weed control on/in walkways, driveways and gravel pathways. In a residential setting, residential adult handlers may be exposed while handling imazapic and both adults and children may be exposed following outdoor applications. Due to the low toxicity of imazapic, quantitative exposure assessments are not required. Residential exposure to imazamic is not expected to increase with this tolerance because this tolerance if for import only. EPA concludes with reasonable certainty that non-occupational exposures to imazapic do not pose a significant human health risk.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to imazapicand any other substances and imazapic does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that imazamox, imazapic, and imazethapyr have a common mechanism of toxicity with other substances. Further information regarding EPA Pesticide Commulative Risk Assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Conclusion.* In the available guideline studies, imazapic exhibited

very low toxicity in mammalian systems, and no effects were seen at doses relevant for human health risk assessment. The database for imazapic is complete. No additional toxicological studies are currently required, and no additional safety factors to protect children are needed.

E. Determination of Safety

Taking into account the available data for imazapic, EPA has concluded that given the low toxicity of this substance, no risks of concern are expected. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to imazapic.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary electrophoresis CE methods (CE method M 3114 and CE method M 2379)) is available for tolerance enforcement. Residues are confirmed by liquid chromatography (LC)/mass spectrometry (MS) analysis.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has established an MRL for residues of imazapic in or on rice, grain at 0.05 ppm which is the same level as the tolerance being established for imazapic in or on rice, grain in the United States. Codex has not established an MRL for imazapic in or on rice, bran.

V. Conclusion

Therefore, tolerances are established for residues of imazapic, (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid) in or on rice, bran at 0.2 ppm and rice, grain at 0.05 ppm.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 25, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

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

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

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

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

■ 2. Amend § 180.490 by adding paragraph (a)(3) to read as follows:

§ 180.490 Imazapic; tolerances for residues.

(a) * * *

(3) Tolerances are established for residues of the herbicide imazapic, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified is to be determined by measuring only imazapic (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid).

TABLE 3 TO PARAGRAPH (a)(3)

Commodity	Parts per million
Rice, bran	0.2
Rice, grain	0.05

* * * * *

[FR Doc. 2023–16613 Filed 8–4–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 8

[CG Docket No. 22–2; DA 23–617; FR ID 157982]

Empowering Broadband Consumers Through Transparency

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) amends its rules to update the template for the recently adopted broadband consumer label. The revised label template reflects a new Affordable Connectivity Program (ACP) application landing page. This action does not modify or otherwise change any entity's underlying responsibilities under the *Broadband Label Order.* It simply ensures that broadband internet access service providers know as early as possible what content must be displayed in the labels.

DATES:

Effective date: September 6, 2023.

Compliance date: FCC will announce compliance dates for the amendments to 47 CFR 8.1(a)(1) by publication of a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Erica H. McMahon, *Erica.McMahon@fcc.gov* or (202) 418–0346, of the Consumer and Governmental Affairs Bureau, Consumer Policy Division. For information regarding the PRA information collection requirements contained in the PRA, contact Cathy Williams, Office of Managing Director, at (202) 418–2918, or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, DA 23–617, CG Docket No. 22–2, adopted and released on July 18, 2023, which requires providers to include the new ACP landing page, *Getinternet.gov*, in their broadband labels. The full text of this document is available online at *https://docs.fcc.gov/public/attachments/DA-23-617A1.pdf.* To request this document in accessible formats for people with disabilities (*e.g.,* Braille, large print, electronic files, audio format) or to request reasonable accommodations (*e.g.,* accessible format documents, sign language interpreters, CART), send an email to *fcc504@fcc.gov* or call the FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice).

Final Paperwork Reduction Act of 1995 Analysis

This document does not contain new or substantively modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

This document may contain non-substantive modifications to an information collection. Any such modifications will be submitted to OMB either: (1) as part of the submission of PRA information collection requirements adopted by the Commission in the *Broadband Label Order* for OMB review; or (2) separately pursuant to OMB's non-substantive modification process.

Congressional Review Act

The Commission sent a copy of document DA 23–617 to Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

Synopsis

In this Order, the Commission modifies its rules to reflect an updated broadband label containing the new ACP landing page of ''*Getinternet.gov.*'' We also make clear that, should a provider be required to display a Spanish version of the label, it must include the Spanish-language landing page for the ACP: *Accedeainternet.gov*. In the *Broadband Label Order,* the Commission stated that ''[t]he label required under § 8.1(a)(1) must be provided in English and in any other languages in which the broadband internet access service provider markets its services in the United States.'' *See* 47 CFR 8.1(a)(4). This change simply ensures the label contains accurate information; it does not involve any policy change.

We find good cause to make this rule change without notice and comment under section 553(b)(B) of the Administrative Procedure Act (APA). *See* 5 U.S.C. 553(b)(3)(B). Section 553(b)(B) of the APA provides exceptions to the notice and comment rulemaking procedures when, among other things, the agency finds good cause that the notice and comment requirements are ''impracticable, unnecessary, or contrary to the public interest'' with respect to the rule at issue. *See* 5 U.S.C. 553(b)(B).

We conclude that, in this case, the substitution of one Commission-supplied URL for a different Commission-supplied URL in broadband providers' labels is insignificant in its nature and impact on regulated entities and beneficial to the broader public by ensuring the use of a URL that serves the intended purpose of the label. The minimal practical significance of the change is particularly true here, given that compliance with the label is not yet required and providers will have ample implementation time (either six months or one year, depending on the size of the provider's subscriber base) following **Federal Register** publication of OMB approval and modification of the codified rule. Similarly, it is in the best interest of providers that they know as early as possible what content must be displayed in the labels as they begin to create the labels. Accordingly, we find, for good cause, that it is ''unnecessary,'' within the meaning of section 553(b)(B), to provide notice and an opportunity for public comment before implementing this rule revision.

Final Regulatory Flexibility Analysis

Because this rule change was adopted without notice and comment, the Regulatory Flexibility Act does not apply.

List of Subjects in 47 CFR Part 8

Cable television, Common carriers, Communications common carriers, Reporting and recordkeeping requirements, Satellites, Telecommunications, Telephone, Radio.

Federal Communications Commission.

Robert Garza,

Legal Advisor, Consumer and Governmental Affairs Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 8 as follows:

PART 8—INTERNET FREEDOM

■ 1. The authority citation for part 8 continues to read as follows:

Authority: 47 U.S.C. 154, 201(b), 257, 303(r), and 1753.

■ 2. Amend § 8.1(a) by revising paragraph (a)(1) to read as follows:

§ 8.1 Transparency.

(a) * * *

(1) Any person providing broadband internet access service shall create and display an accurate broadband consumer label for each stand-alone broadband internet access service it

currently offers for purchase. The label must be prominently displayed, publicly available, and easily accessible to consumers, including consumers with disabilities, at the point of sale with the content and in the format prescribed by the Commission in ''[Fixed or Mobile] Broadband Consumer Disclosure,'' in figure 1 to this paragraph.

Figure 1 to Paragraph (a)(1)—[Fixed or Mobile] Broadband Consumer Disclosure Label

BILLING CODE 6712–01–P

Broadband Facts

Provider Name

Service Plan Name and/or Speed Tier

Fixed or Mobile Broadband Consumer Disclosure

Monthly Price [$]

This Monthly Price [is/is not] an introductory rate. [if introductory rate is applicable, identify length of introductory period and the rate that will apply after introductory period concludes]

This Monthly Price [does not] require[s] a [x year/x month] contract. [only required if applicable; if so, provide link to terms of contract]

Additional Charges & Terms

Provider Monthly Fees [Itemize each fee]	[$]
One-time Fees at the Time of Purchase [Itemize each fee]	[$]
Early Termination Fee	[$]
Government Taxes	Varies by Location

Discounts & Bundles

Click Here for available billing discounts and pricing options for broadband service bundled with other services like video, phone, and wireless service, and use of your own equipment like modems and routers. [Any links to such discounts and pricing options on the provider's website must be provided in this section.]

Affordable Connectivity Program (ACP)

The ACP is a government program to help lower the monthly cost of internet service. To learn more about the ACP, including to find out whether you qualify, visit GetInternet.gov.

Participates in the ACP **[Yes/No]**

Speeds Provided with Plan

Typical Download Speed	**[] Mbps**
Typical Upload Speed	**[] Mbps**
Typical Latency	**[] ms**

Data Included with Monthly Price	**[] GB**
Charges for Additional Data Usage	**[$/GB]**

Network Management	**Read our Policy**
Privacy	**Read our Policy**

Customer Support

Contact Us: example.com/support / (555) 555-5555

Learn more about the terms used on this label by visiting the Federal Communications Commission's Consumer Resource Center.

fcc.gov/consumer

[Unique Plan Identifier Ex. F0005937974123ABC456EMC789]

* * * * *

[FR Doc. 2023–16449 Filed 8–4–23; 8:45 am]

BILLING CODE 6712–01–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 221206–0261]

RIN 0648–BM50

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2023–2024 Biennial Specifications and Management Measures; Inseason Adjustments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule; inseason adjustments to biennial groundfish management measures.

SUMMARY: This final rule announces routine inseason adjustments to management measures in commercial groundfish fisheries. This action is intended to allow fishing vessels to access more abundant groundfish stocks while protecting rebuilding stocks.

DATES: This final rule is effective August 7, 2023.

ADDRESSES: This rule is accessible via the internet at the Office of the Federal Register website at *https://www.federalregister.gov.* Background information and documents are available at the Pacific Fishery Management Council's website at *https://www.pcouncil.org/.*

FOR FURTHER INFORMATION CONTACT: Dr. Sean Matson, phone: 206–526–6187 or email: *sean.matson@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Pacific Coast Groundfish Fishery Management Plan (PCGFMP) and its implementing regulations at title 50 in the Code of Federal Regulations (CFR), part 660, subparts C through G, regulate fishing for over 90 species of groundfish seaward of Washington, Oregon, and California. The Pacific Fishery Management Council (Council) develops groundfish harvest specifications and management measures for 2-year periods (biennia). NMFS published the final rule to implement harvest specifications and management measures for the 2023–2024 biennium for most species managed under the PCGFMP on December 16, 2022 (87 FR 77007). The management measures set at the start of the biennial harvest specifications cycle help the various sectors of the fishery attain, but not exceed, the catch limits for each stock. The Council, in coordination with Pacific Coast Treaty Indian Tribes and the States of Washington, Oregon, and California, recommends adjustments to the management measures during the fishing year to achieve this goal.

At its June 2023 meeting, the Council recommended modifying fixed gear trip limits for limited entry (LE) and open access (OA) fisheries, for bocaccio rockfish (hereafter bocaccio), south of 40°10′ N latitude (lat.), and minimum length limits for LE and OA lingcod south of 42° N lat., after updated information regarding projected catch and attainment became available, as well as requests from industry. Pacific Coast groundfish fisheries are managed using harvest specifications or limits (*e.g.,* overfishing limits [OFL], acceptable biological catch [ABC], annual catch limits [ACL] and harvest guidelines [HG]) recommended biennially by the Council and based on the best scientific information available at that time (50 CFR 660.60(b)). During development of the harvest specifications, the Council also recommends management measures (*e.g.,* trip limits, area closures, and bag limits) that are meant to control catch so as not to exceed the harvest specifications. The harvest specifications and management measures developed for the 2023–2024 biennium used data through the 2021 fishing year. Each of the adjustments to management measures discussed below are based on updated fisheries information that was unavailable when the analysis for the current harvest specifications was completed. As new fisheries data becomes available, adjustments to management measures are projected so as to help harvesters achieve but not exceed the harvest limits.

Bocaccio South of 40°10′ N Latitude

Bocaccio on the West Coast is managed as a separate stock south of 40°10′ N lat., while bocaccio north of 40°10′ N lat. is managed as part of the minor shelf rockfish north of 40°10′ N lat. Bocaccio south of 40°10′ N lat., the subject of this action, is caught both commercially and recreationally, with commercial vessels harvesting it with both trawl and fixed gear (longlines and pots/traps) in the bottom trawl, nearshore, limited entry, and open access fixed gear fisheries. It is caught in shelf and nearshore areas, often together with chilipepper rockfish. The 2023 ACL and harvest guideline for bocaccio south of 40°10′ N lat. are 1,842 metric tons (mt), and 1,793.9 mt, respectively.

At the June 2023 Council meeting, the California Department of Fish and Wildlife (CDFW) received a request from industry to adjust bocaccio bimonthly landing accumulation (''trip'') limits for the open access (OA) fisheries south of 40°10′ N. lat.; to increase the trip limit from 4,000 pounds (1,814 kg) per period (2 month) to 6,000 pounds (2,721 kg) per period. CDFW analyzed the request, as well as increasing the LE trip limits for bocaccio, and recommended the increases to Council. The Council reviewed the analytical documents drafted by the CDFW, as well as the Groundfish Management Team (GMT), and the Groundfish Advisory Subpanel (GAP), to inform their discussion and decision making under the inseason adjustment agenda item.

The intent of increasing trip limits is to increase harvest opportunities, by reducing discard, for vessels catching bocaccio, while targeting chilipepper rockfish. The new OA trip limits would match existing chilipepper trip limits, which are reported to currently be caught in equal amounts to bocaccio. To evaluate potential increases to bocaccio trip limits for both the OA and LE fisheries, the CDFW made model-based catch projections under current regulations and alternative bocaccio trip limits, including the limits ultimately recommended by the Council, beginning on July 1 through the remainder of 2023. Table 1 shows the projected bocaccio landings by fishery, relevant bocaccio allocations, and the projected attainment as a percentage of the landing target, under both the current trip limits and the Council's recommended adjusted trip limits. These projections were based on the most recent catch information available through June 16, 2023.

TABLE 1—PROJECTED LANDINGS, ALLOCATION, AND PROJECTED PERCENTAGE OF BOCACCIO ATTAINED THROUGH 2023 BY TRIP LIMIT AND FISHERY

Option	Fishery	Trip limit	Projected catch (mt)	Projected sum catch (mt)	Percent attainment 2023 non-trawl share (337.8 mt)
Current regulation	LE South of 40°10′ N lat	6,000 lb (2,721 kg)/2 months	16.2	51.6	15
	OA South of 40°10′ N lat	4,000 lb (1,814 kg)/2 months	35.4		
Council-recommended	LE South of 40°10′ N lat	8,000 lb (3,629 kg)/2 months	19.6	65	19
	OA South of 40°10′ N lat	6,000 lb (2,721 kg)/2 months	45.4		

As shown in Table 1, under the current trip limits, the model predicts catch of bocaccio will be at 15 percent, or 51.6 mt of the 337.8 mt commercial non-trawl share for LE and OA fisheries combined, south of 40°10′ N lat.; while under the Council-recommended trip limits, attainment would be 19 percent, or 65 mt of the 337.8 mt commercial non-trawl share, for the LE and OA fisheries combined, south of 40°10′ N lat. Under the Council's recommended trip limits, bocaccio attainment is projected to increase by 4 percent in the LE and OA fisheries south of 40°10′ N lat., from 15 to 19 percent. The Council as a matter of practice, consistently maintains trip limits in LE fisheries at a higher level than those of OA, in order to afford a measure of additional opportunity to fishers with LE permits. Thus, in this case, the bocaccio LE trip limits were also recommended to be raised, to maintain a 2,000 lb (907 kg) per 2 months difference between the LE and OA sectors. Raising the LE trip limits for bocaccio to 8,000 lb (3,629 kg) per 2 months also made them equal to the chilipepper rockfish trip limits (which were reported by industry to be caught in approximately equal amounts), south of 34°27′ N lat.; and close to chilipepper limits between 34°27′ N lat. and 40°10′ N lat., currently 10,000 lb (4,536 kg) per 2 months.

Trip limit increases for bocaccio are intended to increase attainment of the non-trawl harvest guideline (HG), and convert regulatory discard into landed catch. The proposed trip limit increases do not change projected impacts to co-occurring rebuilding species compared to the impacts anticipated in the 2023–2024 harvest specifications because the projected impacts to those species assume that the entire bocaccio ACL is harvested. Therefore, the Council recommended and NMFS is implementing, by modifying Table 2 south to part 660, subpart E, and Table 3 south to part 660, subpart F, trip limit changes for the LE and OA fixed gear fisheries south of 40°10′ N lat. as shown above in Table 1. These changes will start with Period 4 (July and August) and remain in place through the end of 2023 and beyond, unless otherwise modified.

Lingcod

For the June 2023 meeting, the GMT received a request to reduce the lingcod minimum total length limit south of 42° N lat. from 24 inches (61 cm) to 22 inches (56 cm), in groundfish fisheries (both trawl and non-trawl), during periods 4 through 6 of 2023, in order to reduce regulatory discards and increase economic opportunity. Industry reported that constraints from copper and quillback rockfishes off California are leading to nearshore participants to seek more opportunity in the live fish market, which prefers fish smaller than the current commercial limit of 24 inches (61 cm). Lingcod is managed with two separate ACLs, north and south of 40°10′ N lat. The 2023 ACL for lingcod south of 40°10′ N lat. is 726 mt. The limit of 24 inches (61 cm) for commercial fisheries south of 42° N lat. has been in place since 1998.

The intended, and most likely impact of this small change to minimum size length is to convert regulatory discards of slightly smaller fish into landings, resulting in a negligible overall change in overall commercial fishing mortality. Additionally, the ACL for lingcod south of 42° N lat. has shown low attainment (mean of 38, coefficient of variation of 35, and maximum of 60 percent, Table 2) over the past 10 years, and it is highly unlikely that the modest reduction to minimum length would have impacts of any conservation concern. Further, 70–90 percent of lingcod south of 40° 10′ N lat. mortality occurs in the California recreational fishery, for which the size limit is already 22 inches (56 cm); thus, impacts of this action will only affect a small fraction of overall lingcod fishing mortality.

TABLE 2—COMMERCIAL, RECREATIONAL, AND TOTAL MORTALITY OF LINGCOD SOUTH OF 40°10′ N LAT., ALONG WITH ACL AND ACL ATTAINMENT, 2014–2022

Year	Commercial mortality (mt)	Recreational mortality (mt)	Total mortality (mt) [a]	ACL (mt)	ACL attainment (percent)
2014	76	426	510	1,276	40
2015	113	597	718	1,205	60
2016	82	593	682	1,136	60
2017	89	453	552	1,502	37
2018	103	346	457	1,373	33
2019	123	269	397	1,143	35
2020	88	200	290	977	30
2021	82	228	311	1,255	25
2022 [b]	94	226	322	1,334	24

[a] Commercial and recreational mortality may not sum up to the total mortality, because the total mortality values also include mortality from research and non-groundfish fisheries.

[b] 2022 mortality values are a combination of landings data and a 3-year average discard mortality estimate. Final 2022 discard mortality estimates are not available until Fall 2023.

TABLE 3—OPTIONS FOR INSEASON ACTION ON THE LINGCOD SIZE LIMIT SOUTH OF 42° N LAT.

Option	Description
Current regulation	The commercial minimum size limit for lingcod is 24 inches (61 cm) total length south of 42° N lat.
Council recommendation	The commercial minimum size limit for lingcod is 22 inches (56 cm) total length south of 42° N lat.

Minimum size limit changes for lingcod are intended to reduce regulatory discards, increase retention, and potentially marginally increase attainment of the non-trawl, and trawl allocations. The proposed size limit reductions do not change projected impacts to co-occurring rebuilding species (yelloweye rockfish) compared to the impacts anticipated in the 2023–2024 harvest specifications, due a projection of yelloweye bycatch levels assuming the entire lingcod allocation is attained, in the harvest specifications analysis.

The Council recommendation reads to lower ''the minimum lingcod size limit to 22 inches for commercial fisheries south of 42° N lat.''. Groundfish regulations allow for limited retention of bycatch of lingcod in the commercial pink shrimp fishery, and also specifies a minimum size limit for retention of lingcod (currently of 24 inches (61 cm) total length). However, the Council and ancillary bodies did not discuss making a change to lingcod size limits in the pink shrimp fishery, or other non-groundfish fisheries with incidental groundfish catch at the June 2023 meeting. Thus, no changes to the pink shrimp fishery regulations are implemented within this rule.

Therefore, the Council recommended and NMFS is implementing, by modifying Table 2 North, and South to part 660, subpart E, and Table 3 North, and South to part 660, subpart F, minimum size limit changes for LE and OA lingcod south of 42° N lat. as shown above in Table 3. These changes will start with Period 4 (July and August) and remain in place through the end of 2023 and beyond, unless otherwise modified.

The regulation text is also revised in § 660.60, paragraph (h)(5)(ii)(A)(*2*)(*ii*) to read as follows: ''South of 42° N lat., for lingcod with the head removed, the minimum size limit is 18 inches (46 cm), which corresponds to 22 inches (56 cm) total length for whole fish'' (limited entry fixed gear and open access); and in § 660.60, paragraph (h)(5)(ii)(B)(*2*)(*ii*) to read as follows: ''The minimum size limit for lingcod South of 42° N lat. is 22 inches (56 cm) total length for whole fish, which corresponds to 18 inches (46 cm) with the head removed'' (shorebased IFQ fishery).

Classification

This final rule makes routine inseason adjustments to groundfish fishery management measures, based on the best scientific information available, consistent with the PCGFMP and its implementing regulations.

This action is taken under the authority of 50 CFR 660.60(c) and is exempt from review under Executive Order 12866.

The aggregate data upon which these actions are based, are available for public inspection by contacting Dr. Sean Matson in NMFS West Coast Region (see **FOR FURTHER INFORMATION CONTACT,** above), or view at the NMFS West Coast Groundfish website: *https://www.fisheries.noaa.gov/species/west-coast-groundfish.*

Pursuant to 5 U.S.C. 553(b), NMFS finds good cause to waive prior public notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. The adjustments to management measures in this document increase trip limits and decrease size limits for fisheries off California to allow additional economic opportunity while keeping catch within allocations established by the 2023–2024 harvest specifications. The trip limit increases are for the LE and OA sectors for bocaccio south of 40°10′ N lat. Over the year 2023, these changes are projected to potentially increase economic value of the fisheries for bocaccio alone, by $18,519 for LE and $40,565 for OA, as well as reduce regulatory discards in these fisheries. The decreases to minimum length limits for lingcod off California fishery are needed to provide alternative opportunity due to conservation related constraints in the nearshore, in the form of smaller lingcod which are preferred for live markets; and to convert regulatory discards to landed catch. No aspect of this action is controversial, and changes of this nature were anticipated in the final rule for the 2023–2024 harvest specifications and management measures which published on December 16, 2022 (87 FR 77007).

Delaying implementation to allow for public comment would likely reduce the economic benefits to the commercial fishing industry and the businesses that rely on that industry, because it is unlikely the new regulations would publish and could be implemented in time to realize the projected benefits to fishing communities and the resource. A delay in implementation could also contribute to unnecessarily discarded and largely wasted fish, which could otherwise be landed to provide food and revenue, and responsible use of the resource. Therefore, providing a comment period for this action could significantly limit the economic benefits to the fishery, and would hamper the achievement of optimum yield from the affected fisheries.

Therefore, the NMFS finds reason to waive the 30-day delay in effectiveness pursuant to 5 U.S.C. 553(d)(1) so that this final rule may become effective upon publication in the **Federal Register**. The adjustments to management measures in this document affect fisheries by increasing opportunity and allowing greater economic benefit. These adjustments were requested by the Council's advisory bodies, as well as members of industry during the Council's June 2023 meeting, and recommended unanimously by the Council. No aspect of this action is controversial, and changes of this nature were anticipated in the biennial harvest specifications and management measures established through a notice and comment rulemaking for 2023–2024 (87 FR 77007).

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Indian fisheries.

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

Dated: August 1, 2023.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660–FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.60, revise paragraph (h)(5)(ii)(A)(*2*)(*ii*) and (h)(5)(ii)(B)(2)(*ii*) to read as follows:

§ 660.60 Specifications and management measures.

* * * * *

(h) * * *

(5) * * *

(ii) * * *

(A) * * *

(*2*) * * *

(*ii*) South of 42° N lat., for lingcod with the head removed, the minimum size limit is 18 inches (46 cm), which corresponds to 22 inches (56 cm) total length for whole fish.

* * * * *

(B) * * *

(2) * * *

(*ii*) The minimum size limit for lingcod South of 42° N lat. is 22 inches (56 cm) total length for whole fish, which corresponds to 18 inches (46 cm) with the head removed.

* * * * *

■ 3. Revise Table 2 (North) to part 660, subpart E, to read as follows:

BILLING CODE 3510–22–P

Table 2 (North) to Part 660, Subpart E -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear North of 40°10' N lat.

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table 7/1/2023

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
Rockfish Conservation Area (RCA)[1/]:							
1	North of 46°16' N lat.	shoreline - 100 fm line[1/]					
2	46°16' N lat. - 40°10' N lat.	30 fm line[1/] - 100 fm line[1/]					
See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Bank, and EFHCAs).							
State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.							
3	**Minor Slope Rockfish[2/] & Darkblotched rockfish**	8,000 lb/ 2 months					
4	**Pacific ocean perch**	3,600 lb/ 2 months					
5	**Sablefish**	4,500 lb/ week, not to exceed 9,000 lb /2 months					
6	**Longspine thornyhead**	10,000 lb/ 2 months					
7	**Shortspine thornyhead**	2,000 lb/ 2 months			2,500 lb/ 2 months		
8	**Dover sole, arrowtooth flounder, petrale**	10,000 lb/ month					
9	**sole, English sole, starry flounder, Other**						
10	**Flatfish[3/ 7/]**						
11	**Whiting**	10,000 lb/ trip					
12	**Minor Shelf Rockfish[2/]**	800 lb/ month					
13	**Widow rockfish**	4,000 lb/ 2 months					
14	**Yellowtail rockfish**	3,000 lb/ month					
15	**Canary rockfish**	4,000 lb/ 2 months					
16	**Yelloweye rockfish**	CLOSED					
17	**Minor Nearshore Rockfish, Oregon black/blue/deacon rockfish, & black rockfish[4/]**						
18	North of 42°00' N lat.	5,000 lb/ 2 months, no more than 1,200 lb of which may be species other than black rockfish or blue/deacon rockfish[3/]					
19	42°00' N lat. - 40°10' N lat. Minor Nearshore Rockfish	2,000 lb/ 2 months, of which no more than 75 lb may be quillback rockfish, and of which no more than 75 lb may be copper rockfish					
20	42°00' N lat. - 40°10' N lat. Black Rockfish	7,000 lb/ 2 months					
21	**Lingcod[5/]**						
22	North of 42°00' N lat.	7,000 lb/ 2 months					
23	42°00' N lat. - 40°10' N lat.	2, 000 lb/ 2 months					
24	**Pacific cod**	1,000 lb/ 2 months					
25	**Spiny dogfish**	200,000 lb/ 2 months		150,000 lb/ 2 months	100,000 lb/ 2 months		
26	**Longnose skate**	Unlimited					
27	**Other Fish[6/]& Cabezon in California**	Unlimited					
28	**Oregon Cabezon/Kelp Greenling**	Unlimited					
29	**Big skate**	Unlimited					

TABLE 2 (North)

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ Minor Shelf and Slope Rockfish complexes are defined at § 660.11. Bocaccio, chilipepper and cowcod are included in the trip limits for Minor Shelf Rockfish. Splitnose rockfish is included in the trip limits for Minor Slope Rockfish.

3/ "Other flatfish" are defined at § 660.11 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ For black rockfish north of Cape Alava (48°09.50' N lat.), and between Destruction Is. (47°40' N lat.) and Leadbetter Pnt. (46°38.17' N lat.), there is an additional limit of 100 lb or 30 percent by weight of all fish on board, whichever is greater, per vessel, per fishing trip.

5/ The minimum size limit for lingcod is 22 inches (56 cm) total length North of 42° N lat. and 22 inches (56 cm) total length South of 42° N lat.

6/ "Other Fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

7/ LEFG vessels may be allowed to fish inside groundfish conservation areas using hook and line only. See § 660.230 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

■ 4. Revise Table 2 (South) to part 660, subpart E, to read as follows:

Table 2 (South) to Part 660, Subpart E -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear South of 40°10' N lat.
Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table 7/1/2023

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
	Rockfish Conservation Area (RCA)[1/]:						
1	40°10' N lat. - 38°57.5' N lat.	40 fm line[1/] - 125 fm line[1/]					
2	38°57.5' N lat. -34°27' N lat.	50 fm line[1/] - 125 fm line[1/]					
3	South of 34°27' N lat.	100 fm line[1/] - 150 fm line[1/] (also applies around islands)					
	See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Banks, and EFHCAs).						
	State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
4	**Minor Slope rockfish[2/] & Darkblotched rockfish**	40,000 lb/ 2 months, of which no more than 6,000 lb may be blackgill rockfish					
5	**Splitnose rockfish**	40,000 lb/ 2 months					
6	**Sablefish**						
7	40°10' N lat. - 36°00' N lat.	4,500 lb/ week, not to exceed 9,000 lb /2 months					
8	South of 36°00' N lat.	2,500 lb/ week					
9	**Longspine thornyhead**	10,000 lb/ 2 months					
10	**Shortspine thornyhead**						
11	40°10' N lat. - 34°27' N lat.	2,000 lb/ 2 months			2,500 lb/ 2 months		
12	South of 34°27' N lat.	3,000 lb/ 2 months					
13 14 15	**Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish[3/8/]**	10,000 lb/ month					
16	**Whiting**	10,000 lb/ trip					
17	**Minor Shelf Rockfish[2/]**						
18	40°10' N lat. - 34°27' N lat.	8,000 lb/ 2 months, of which no more than 500 lb may be vermilion					
19	South of 34°27' N lat.	5,000 lb/ 2 months, of which no more than 3,000 lb may be vermilion					
20	**Widow**						
21	40°10' N lat. - 34°27' N lat.	10,000 lb/ 2 months					
22	South of 34°27' N lat.	8,000 lb/ 2 months					
23	**Chilipepper**						
24	40°10' N lat. - 34°27' N lat.	10,000 lb. / 2 months					
25	South of 34°27' N lat.	8,000 lb. / 2 months					
26	**Canary rockfish**	4,000 lb/ 2 months					
27	**Yelloweye rockfish**	CLOSED					
28	**Cowcod**	CLOSED					
29	**Bronzespotted rockfish**	CLOSED					
30	**Bocaccio**	8,000 lb/ 2 months					
31	**Minor Nearshore Rockfish**						
32	Shallow nearshore[4/]	2,000 lb/ 2 months					
33	Deeper nearshore[5/]	2,000 lb/ 2 months, of which no more than 75 lb may be quillback rockfish, and of which no more than 75 lb may be copper rockfish					
34	**California Scorpionfish**	3,500 lb/ 2 months					
35	**Lingcod[6/]**	1,600 lb / 2 months					
36	**Pacific cod**	1,000 lb/ 2 months					
37	**Spiny dogfish**	200,000 lb/ 2 months		150,000 lb/ 2 months	100,000 lb/ 2 months		
38	**Longnose skate**	Unlimited					
39	**Other Fish[7/] & Cabezon in California**	Unlimited					
40	**Big Skate**	Unlimited					

TABLE 2 (South)

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ Minor Shelf and Slope Rockfish complexes are defined at § 660.11. Pacific ocean perch is included in the trip limits for Minor Slope Rockfish. Blackgill rockfish have a species specific trip sub-limit within the Minor Slope Rockfish cumulative limit. Yellowtail rockfish are included in the trip limits for Minor Shelf Rockfish. Bronzespotted rockfish have a species specific trip limit.

3/ "Other Flatfish" are defined at § 660.11 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ "Shallow Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*1*).

5/ "Deeper Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*2*).

6/ The commercial mimimum size limit for lingcod is 22 inches (56 cm) total length South of 42° N lat.

7/ "Other Fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

8/ LEFG vessels may be allowed to fish inside groundfish conservation areas using hook and line only. See § 660.230 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

■ 5. Revise Table 3 (North) to part 660, subpart F, to read as follows:

Table 3 (North) to Part 660, Subpart F -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Open Access Gears North of 40°10' N lat.

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table

7/1/2023

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
	Rockfish Conservation Area (RCA)[1/]:						
1	North of 46°16' N lat.	shoreline - 100 fm line[1/]					
2	46°16' N lat. - 40°10' N lat.	30 fm line[1/] - 100 fm line[1/]					
	See §§660.60, 660.330 and 660.333 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Bank, and EFHCAs).						
	State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
3	**Minor Slope Rockfish[2/] & Darkblotched rockfish**	2,000 lb/ month					
4	**Pacific ocean perch**	100 lb/ month					
5	**Sablefish**	3,000 lb/ week, not to exceed 6,000 lb/ 2 months					
6	**Shortpine thornyheads**	50 lb/ month					
7	**Longspine thornyheads**	50 lb/ month					
8 9 10	**Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish[3/ 7/]**	5,000 lb/ month					
11	**Whiting**	300 lb/ month					
12	**Minor Shelf Rockfish[2/]**	800 lb/ month					
13	**Widow rockfish**	2,000 lb/ 2 months					
14	**Yellowtail rockfish**	1,500 lb/ month					
15	**Canary rockfish**	2,000 lb/ 2 months					
16	**Yelloweye rockfish**	CLOSED					
17	**Minor Nearshore Rockfish, Oregon black/blue/deacon rockfish, & black rockfish**						
18	North of 42°00' N lat.	5,000 lb/ 2 months, no more than 1,200 lb of which may be species other than black rockfish or blue/deacon rockfish[4/]					
19	42°00' N lat. - 40°10' N lat. Minor Nearshore Rockfish	2,000 lb/ 2 months, of which no more than 75 lb may be quillback rockfish, and of which no more than 75 lb may be copper rockfish					
20	42°00' N lat. - 40°10' N lat. Black rockfish	7,000 lb/ 2 months					
21	**Lingcod[5/]**						
22	North of 42°00' N lat.	3,500 lb/ month					
23	42°00' N lat. - 40°10' N lat.	1,000 lb/ month					
24	**Pacific cod**	1,000 lb/ 2 months					
25	**Spiny dogfish**	200,000 lb/ 2 months		150,000 lb/ 2 months	100,000 lb/ 2 months		
26	**Longnose skate**	Unlimited					
27	**Big skate**	Unlimited					
28	**Other Fish[6/] & Cabezon in California**	Unlimited					
29	**Oregon Cabezon/Kelp Greenling**	Unlimited					
30	**SALMON TROLL** *(subject to RCAs when retaining all species of groundfish, except for yellowtail rockfish and lingcod, as described below)*						
31	North	*Salmon trollers may retain and land up to 500 lb of yellowtail rockfish per month as long as salmon is on board, both within and outside of the RCA. Salmon trollers may retain and land up to 1 lingcod per 2 Chinook per trip, plus 1 lingcod per trip, up to a trip limit of 10 lingcod, on a trip where any fishing occurs within the RCA. The lingcod limit only applies during times when lingcod retention is allowed, and is not "CLOSED." Theses limits are within the per month limits described in the table above, and not in addition to those limits. All groundfish species are subject to the open access limits, seasons, size limits and RCA restrictions listed in the table above, unless otherwise stated here.*					
32	**PINK SHRIMP NON-GROUNDFISH TRAWL** *(not subject to RCAs)*						
33	North	Effective April 1 - October 31: Groundfish: 500 lb/day, multiplied by the number of days of the trip, not to exceed 1,500 lb/trip. The following sublimits also apply and are counted toward the overall 500 lb/day and 1,500 lb/trip groundfish limits: lingcod 300 lb/month (minimum 24 inch size limit); sablefish 2,000 lb/month; canary, thornyheads and yelloweye rockfish are PROHIBITED. All other groundfish species taken are managed under the overall 500 lb/day and 1,500 lb/trip groundfish limits. Landings of these species count toward the per day and per trip groundfish limits and do not have species-specific limits. The amount of groundfish landed may not exceed the amount of pink shrimp landed.					

TABLE 3 (North)

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ Minor Shelf and Slope Rockfish complexes are defined at § 660.11. Bocaccio, chilipepper and cowcod rockfishes are included in the trip limits for Minor Shelf Rockfish. Splitnose rockfish is included in the trip limits for Minor Slope Rockfish.

3/ "Other flatfish" are defined at § 660.11 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ For black rockfish north of Cape Alava (48°09.50' N lat.), and between Destruction Is. (47°40' N lat.) and Leadbetter Pnt. (46°38.17' N lat.), there is an additional limit of 100 lbs or 30 percent by weight of all fish on board, whichever is greater, per vessel, per fishing trip.

5/ The minimum size limit for lingcod is 22 inches (56 cm) total length North of 42° N lat. and 22 inches (56 cm) South of 42° N lat.

6/ "Other fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

7/ Open access vessels may be allowed to fish inside groundfish conservation areas using hook and line only. See § 660.330 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

■ 6. Revise Table 3 (South) to part 660, subpart F, to read as follows:

Table 3 (South) to Part 660, Subpart F -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Open Access Gears South of 40°10' N lat.

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table 7/1/2023

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
	Rockfish Conservation Area (RCA)[1/]:						
1	40°10' N lat. - 38°57.5' N lat.	40 fm line[1/] - 125 fm line[1/]					
2	38°57.5' N lat. -34°27' N lat.	50 fm line[1/] - 125 fm line[1/]					
3	South of 34°27' N lat.	100 fm line[1/] - 150 fm line[1/] (also applies around islands)					
	See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Banks, and EFHCAs).						
	State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
4	**Minor Slope Rockfish[2/] & Darkblotched rockfish**	10,000 lb/ 2 months, of which no more than 2,500 lb may be blackgill rockfish					
5	**Splitnose rockfish**	200 lb/ month					
6	**Sablefish**						
7	40°10' N lat. - 36°00' N lat.	3,000 lb/ week, not to exceed 6,000 lb/ 2 months					
8	South of 36°00' N lat.	2,000 lb/ week, not to exceed 6,000 lb/ 2 months					
9	**Shortpine thornyheads**						
10	40°10' N lat. - 34°27' N lat.	50 lb/ month					
11	**Longspine thornyheads**						
12	40°10' N lat. - 34°27' N lat.	50 lb/ month					
13	**Shortpine thornyheads and longspine thornyheads**						
14	South of 34°27' N lat.	100 lb/ day, no more than 1,000 lb/ 2 months					
15	**Dover sole, arrowtooth flounder, petrale**						
16	**sole, English sole, starry flounder, Other**	5,000 lb/ month					
17	**Flatfish[3/8/]**						
18	**Whiting**	300 lb/ month					
19	**Minor Shelf Rockfish[2/]**						
20	40°10' N lat. - 34°27' N lat.	4,000 lb/ 2 months, of which no more than 400 lb may be vermilion					
21	South of 34°27' N lat.	3,000 lb/ 2 months, of which no more than 1,200 lb may be vermilion					
22	**Widow rockfish**						
23	40°10' N lat. - 34°27' N lat.	6,000 lb/ 2 months					
24	South of 34°27' N lat.	4,000 lb/ 2 months					
25	**Chilipepper**						
26	40°10' N lat. - 34°27' N lat.	6,000 lb/ 2 months					
27	South of 34°27' N lat.	4,000 lb/ 2 months					
28	**Canary rockfish**	2,000 lb/ 2 months					
29	**Yelloweye rockfish**	CLOSED					
30	**Cowcod**	CLOSED					
31	**Bronzespotted rockfish**	CLOSED					
32	**Bocaccio**	6,000 lb/ 2 months					
33	**Minor Nearshore Rockfish**						
34	Shallow nearshore[4/]	2,000 lb/ 2 months					
35	Deeper nearshore[5/]	2,000 lb/ 2 months, of which no more than 75 lb may be quillback rockfish, and of which no more than 75 lb may be copper rockfish					
36	**California Scorpionfish**	3,500 lb/ 2 months					
37	**Lingcod[6/]**	700 lb / month					
38	**Pacific cod**	1,000 lb/ 2 months					
39	**Spiny dogfish**	200,000 lb/ 2 months		150,000 lb/ 2 months	100,000 lb/ 2 months		
40	**Longnose skate**	Unlimited					
41	**Big skate**	Unlimited					
42	**Other Fish[7/] & Cabezon in California**	Unlimited					

TABLE 3 (South)

Table 3 (South) Continued

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table 7/1/2023

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
Rockfish Conservation Area (RCA)[1/]:							
43	40°10' N lat. - 38°57.5' N lat.	40 fm line[1/] - 125 fm line[1/]					
44	38°57.5' N lat. -34°27' N lat.	50 fm line[1/] - 125 fm line[1/]					
45	South of 34°27' N lat.	100 fm line[1/] - 150 fm line[1/] (also applies around islands)					
See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Banks, and EFHCAs).							
46	**SALMON TROLL** *(subject to RCAs when retaining all species of groundfish, except for yellowtail rockfish, as described below)*						
47	South of 40°10' N lat.	Salmon trollers may retain and land up to 1 lb of yellowtail rockfish for every 2 lb of Chinook salmon landed, with a cumulative limit of 200 lb/month, both within and outside of the RCA. This limit is within the 4,000 lb per 2 month limit for minor shelf rockfish between 40°10' and 34°27' N lat., and not in addition to that limit. All groundfish species are subject to the open access limits, seasons, size limits and RCA restrictions listed in the table above, unless otherwise stated here.					
48	**RIDGEBACK PRAWN AND, SOUTH OF 38°57.50' N lat., CA HALIBUT AND SEA CUCUMBER NON-GROUNDFISH TRAWL**						
49	**NON-GROUNDFISH TRAWL Rockfish Conservation Area (RCA) for CA Halibut, Sea Cucumber & Ridgeback Prawn:**						
50	*40°10' N lat. - 38°00' N lat.*	*100 fm line[1/] - 200 fm line[1/]*		*100 fm line[1/] - 150 fm line[1/]*			*100 fm line[1/] - 200 fm line[1/]*
51	*38°00' N lat. - 34°27' N lat.*	*100 fm line[1/] - 150 fm line[1/]*					
52	*South of 34°27' N lat.*	*100 fm line[1/] - 150 fm line[1/]*					
53		Groundfish: 300 lb/trip. Species-specific limits described in the table above also apply and are counted toward the 300 lb groundfish per trip limit. The amount of groundfish landed may not exceed the amount of the target species landed, except that the amount of spiny dogfish landed may exceed the amount of target species landed. Spiny dogfish are limited by the 300 lb/trip overall groundfish limit. The daily trip limits for sablefish coastwide and thornyheads south of Pt. Conception and the overall groundfish "per trip" limit may not be multiplied by the number of days of the trip. Vessels participating in the California halibut fishery south of 38°57.50' N lat. are allowed to (1) land up to 100 lb/day of groundfish without the ratio requirement, provided that at least one California halibut is landed and (2) land up to 3,000 lb/month of flatfish, no more than 300 lb of which may be species other than Pacific sanddabs, sand sole, starry flounder, rock sole, curlfin sole, or California scorpionfish (California scorpionfish is also subject to the trip limits and closures in line 29).					
54	**PINK SHRIMP NON-GROUNDFISH TRAWL GEAR** *(not subject to RCAs)*						
55	South	Effective April 1 - October 31: Groundfish: 500 lb/day, multiplied by the number of days of the trip, not to exceed 1,500 lb/trip. The following sublimits also apply and are counted toward the overall 500 lb/ day and 1,500 lb/ trip groundfish limits: lingcod 300 lb/ month (minimum 24 inch size limit); sablefish 2,000 lb/ month; canary rockfish, thornyheads and yelloweye rockfish are PROHIBITED. All other groundfish species taken are managed under the overall 500 lb/day and 1,500 lb/ trip groundfish limits. Landings of all groundfish species count toward the per day, per trip or other species-specific sublimits described here and the species-specific limits described in the table above do not apply. The amount of groundfish landed may not exceed the amount of pink shrimp landed.					

TABLE 3 (South) Continued

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ Minor Shelf and Slope Rockfish complexes are defined at § 660.11. Pacific ocean perch is included in the trip limits for minor slope rockfish. Blackgill rockfish have a species specific trip sub-limit within the minor slope rockfish cumulative limits. Yellowtail rockfish is included in the trip limits for minor shelf rockfish. Bronzespotted rockfish have a species specific trip limit.

3/ "Other flatfish" are defined at § 660.11 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ "Shallow Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*1*).

5/ "Deeper Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*2*).

6/ The commercial mimimum size limit for lingcod is 22 inches (56 cm) South of 42° N lat.

7/ "Other fish" are defined at § 660.11 and includes kelp greenling off California and leopard shark.

8/ Open access vessels may be allowed to fish inside groundfish conservation areas using hook and line only. See § 660.330 (d) of the regulations for more information.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

[FR Doc. 2023–16720 Filed 8–2–23; 4:15 pm]

BILLING CODE 3510–22–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 230224–0053]

RTID 0648–XD088

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Using Jig Gear in the Western Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels using jig gear in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2023 total allowable catch (TAC) of Pacific cod by vessels using jig gear in the Western Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), August 2, 2023, through 2400 hours, A.l.t., December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Krista Milani, 907–581–2062.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2023 Pacific cod TAC apportioned to vessels using jig gear in the Western Regulatory Area of the GOA is 131 metric tons (mt) as established by the final 2023 and 2024 harvest specifications for groundfish in the GOA (88 FR 13238, March 2, 2023).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the 2023 Pacific cod TAC apportioned to vessels using jig gear in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 130 mt and is setting aside the remaining 1 mt as bycatch to support other anticipated groundfish fisheries. In accordance with

§ 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels using jig gear in the Western Regulatory Area of the GOA.

While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of Pacific cod by vessels using jig gear in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 01, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 2, 2023.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–16841 Filed 8–2–23; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 150
Monday, August 7, 2023

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1400; Project Identifier AD–2022–01374–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 737–8 and 737–9 airplanes. This proposed AD was prompted by a determination that the loss of ground through the P6 panel results in the failure of the standby power control unit (SPCU). The loss of the SPCU and P6 would result in the loss of significant flight crew instrumentation and displays. This proposed AD would require installing two bonding jumpers from the P6 panel structure to primary structure. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 21, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1400; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* by searching for and locating Docket No. FAA–2023–1400.

FOR FURTHER INFORMATION CONTACT: Hien T. Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3977; email: *Hien.T.Nguyen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–1400; Project Identifier AD–2022–01374–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Hien T. Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3977; email: *Hien.T.Nguyen@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has received a report indicating that the loss of a ground through the P6 panel results in the failure in the SPCU. The SPCU provides AC and DC electrical power in the event there is a loss of power provided by primary electrical sources. Currently, there is a single ground strap between the P6 structure and airplane primary structure. This design was carried over to the 737 MAX airplanes from the 737 NG airplanes. The SPCU tray on the 737 MAX airplanes has an inherent bond path through the P6 structure. However, the requirements for redundant grounds to the SPCU tray did not flow down to include redundant grounds through the P6 panel to airplane primary structure. During a bonding analysis, it was determined that separate redundant ground paths from the two ground blocks on the SPCU tray to airplane primary structure are required in order to prevent a single point of failure condition, which could result in a potentially confusing combination of flight deck effects and a combination of

lost functionality. This condition, if not addressed, would result in loss of significant flightcrew instrumentation and displays and may lead to loss of continued safe flight and landing (CSFL).

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 737–24A1248 RB, dated May 16, 2022. This service information specifies procedures to install new bonding jumpers from the P6 panel structure to the primary structure to provide a redundant ground path for the SPCU.

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described, except for any differences identified as exceptions in the regulatory text of this proposed AD. For information on the procedures and compliance times, see this service information at *regulations.gov* under Docket No. FAA–2023–1400.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 79 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Install two bonding jumpers	3 work-hour × $85 per hour = $255	$180	$435	$34,365

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2023–1400; Project Identifier AD–2022–01374–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 21, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–8 and 737–9 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 737–24A1248 RB, dated May 16, 2022.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Unsafe Condition

This AD was prompted by a determination that the loss of ground through the P6 panel results in the failure of the standby power control unit (SPCU). The loss of the SPCU and P6 would result in the loss of significant flight crew instrumentation and displays. It was determined that separate redundant ground paths from the two ground blocks on the SPCU tray to airplane primary structure are required in order to prevent a single point of failure condition. The FAA is issuing this AD to address loss of the SPCU and P6 panel. The unsafe condition, if not addressed, would result in the loss of significant flightcrew instruments and displays, and may lead to loss of continued safe flight and landing.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 737–24A1248 RB, dated May 16, 2022, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–24A1248 RB, dated May 16, 2022.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 737–24A1248, dated May 16, 2022, which is referred to in Boeing Alert Requirements Bulletin 737–24A1248 RB, dated May 16, 2022.

(h) Exceptions to Service Information Specifications

Where the Compliance Time column of the table in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 737–24A1248 RB, dated May 16, 2022, uses the phrase ''the original issue date of Requirements Bulletin 737–24A1248 RB,'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

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

(j) Related Information

(1) For more information about this AD, contact Hien T. Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3977; email: *Hien.T.Nguyen@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (k)(3) and (4) of this AD.

(k) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 737–24A1248 RB, dated May 16, 2022.

(ii) [Reserved]

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

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

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

Issued on July 31, 2023.

Victor Wicklund,

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

[FR Doc. 2023–16644 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 5, 301, and 602

[REG–134420–10]

RIN 1545–BJ87

Revising Consolidated Return Regulations To Reflect Statutory Changes, Modernize Language, and Enhance Clarity

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; withdrawal of notices of proposed rulemaking; partial withdrawal of notices of proposed rulemaking; and proposed withdrawal of temporary regulations.

SUMMARY: This document contains proposed amendments to regulations applicable to affiliated groups of corporations that file consolidated Federal income tax returns. The proposed regulations would modify those regulations to reflect statutory changes, update language to remove antiquated or regressive terminology, and enhance clarity. Additionally, this document partially or completely withdraws certain notices of proposed rulemaking and proposes to withdraw certain temporary regulations. The proposed regulations would affect corporations filing consolidated returns.

DATES: As of August 7, 2023, the notices of proposed rulemaking published on November 14, 2001 (66 FR 57021), March 12, 2002 (67 FR 11070), May 31, 2002 (67 FR 38039), May 31, 2002 (67 FR 38040), March 14, 2003 (68 FR 12324), May 7, 2003 (68 FR 24404), March 18, 2004 (69 FR 12811), August 18, 2004 (69 FR 51209), August 26, 2004 (69 FR 52462), April 10, 2007 (72 FR 17814), and June 23, 2010 (75 FR 35710) are withdrawn. As of August 7, 2023, the notices of proposed rulemaking published on December 30, 1992 (57 FR 62251–01), March 18, 2004 (69 FR 12281), and June 11, 2015 (80 FR 33211) are partially withdrawn (see **SUPPLEMENTARY INFORMATION** for specific details). Written or electronic comments as well as requests for a public hearing must be received by November 6, 2023. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–134420–10). Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment submitted to its public docket.

Send paper submissions to: CC:PA:LPD:PR (REG–134420–10), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, William W. Burhop at (202) 317–5363 or Kelton P. Frye at (202) 317–5135 (not toll-free numbers); concerning the submission of comments and/or requests for a public hearing, Vivian Hayes by email at *publichearings@irs.gov* or by phone at (202) 317–5306 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This notice of proposed rulemaking (NPRM) contains proposed regulations under sections 1502, 1503, 1552, and 1563 of the Internal Revenue Code of 1986 (Code). These proposed regulations primarily would revise the Income Tax Regulations (26 CFR part 1) under section 1502 (consolidated return regulations). Section 1502 authorizes the Secretary of the Treasury or the Secretary's delegate (Secretary) to prescribe consolidated return regulations for an affiliated group of corporations that join in filing (or that are required to join in filing) a consolidated return (consolidated group) to clearly reflect the Federal income tax liability of the consolidated group and to prevent avoidance of such tax liability. *See* § 1.1502–1(h) (defining the term ''consolidated group''). For purposes of carrying out those objectives, section 1502 also permits the

Secretary to prescribe rules that may be different from the provisions of chapter 1 of the Code (chapter 1) that would apply if the corporations composing the consolidated group filed separate returns. Terms used in the consolidated return regulations generally are defined in § 1.1502–1.

The proposed regulations also would revise or propose to remove other regulations under the Code. These regulations are set forth in (i) the Income Tax Regulations (26 CFR part 1), (ii) the Temporary Income Tax Regulations under the Revenue Act of 1978 (26 CFR part 5), (iii) the Regulations on Procedure and Administration (26 CFR part 301), and (iv) the OMB Control Numbers under the Paperwork Reduction Act Regulations (26 CFR part 602).

Explanation of Provisions

I. Overview

In this NPRM, the Treasury Department and the IRS have proposed revisions to the consolidated return regulations to (i) eliminate obsolete or otherwise outdated provisions, (ii) modernize the language and improve the clarity of the regulations, and (iii) facilitate taxpayer compliance. As an initial matter, the proposed regulations would update the consolidated return regulations to reflect statutory changes made by legislation enacted during the last 50-plus years and remove consolidated return regulations that have no practical applicability to taxpayers. The proposed regulations also would revise the consolidated return regulations to eliminate obsolete or otherwise incorrect terms and cross-references. Lastly, the proposed regulations generally would remove transition rules for transactions occurring in or before 2009 because the taxable years affected by such transition rules generally are closed and the rules have no practical applicability to taxpayers.

The proposed regulations also would update the consolidated return regulations and the regulations under section 1563 to eliminate antiquated or regressive terminology. For example, the proposed regulations would replace all gender-specific pronouns and other identifiers in the consolidated return regulations with gender-neutral pronouns and identifiers. The proposed regulations also would revise the consolidated regulations to identify (i) American Samoa, (ii) the Commonwealth of the Northern Mariana Islands, (iii) the Commonwealth of Puerto Rico, (iv) Guam, and (v) the U.S. Virgin Islands as ''territories'' of the United States rather than ''possessions.'' Each of those jurisdictions has its own government and its own tax system. These revisions are consistent with, and in furtherance of, the Treasury Department's Equity Action Plan, as well as Executive Order 13985 of January 20, 2021, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,* 86 FR 7009 (January 25, 2021).

The proposed regulations also withdraw or partially withdraw numerous NPRMs. These NPRMs include: (i) NPRMs that are incorporated, in revised form, into these proposed regulations or that were incorporated into final regulations in revised form; (ii) a NPRM that became obsolete when proposed regulations provided in a subsequent, discrete NPRM were adopted as final regulations; and (iii) NPRMs that cross-referenced temporary regulations (the text of which served as the text for those proposals) that were removed, have expired, or otherwise have become obsolete. Additionally, the proposed regulations propose to withdraw temporary regulations that (i) no longer have practical applicability to taxpayers, or (ii) would be replaced by final regulations proposed by this document.

With regard to each provision of the consolidated return regulations that these proposed regulations would remove, the Treasury Department and the IRS generally have proposed to reserve the affected provision. This approach is intended solely to avoid cascading changes to cross-references throughout the consolidated return regulations, thereby preserving historical citations and reducing potential confusion for taxpayers. Accordingly, the reserving of those provisions does not indicate in any manner that the Treasury Department and the IRS are studying, or intend to study, any of the one or more topics addressed by the reserved provision.

Lastly, the proposed regulations would remove numerous provisions that cross-reference prior-law editions of the Code of Federal Regulations (CFR). Following adoption of the proposed regulations as final regulations, taxpayers may consult the CFR for a particular year to determine the rules applicable to that year.

The Treasury Department and the IRS request comments on whether any aspect of the proposed regulations would effectuate a substantive revision of the consolidated return regulations, as opposed to a mere update or similar modification. Additionally, comments are requested on whether any provision proposed to be removed or revised by this document should be retained in its form as of August 4, 2023. Lastly, the Treasury Department and the IRS request comments identifying any other provision of the consolidated return regulations that should be revised consistent with the scope of the proposed regulations, such as additional provisions of the consolidated return regulations that are obsolete or otherwise outdated.

II. Summary of Proposed Changes

A. Removal of Regulations That Implement Repealed Statutory Provisions

The proposed regulations would remove provisions of the consolidated return regulations that have been rendered obsolete by enacted legislation.

1. Section 1.1502–1 (Definitions)

Sections 1.1502–1(f)(2) and (3) currently reference section 1562 of the Internal Revenue Code of 1954 (1954 Code), which allowed controlled groups of corporations (as defined in section 1563(a) of the 1954 Code) to elect multiple surtax exemptions. Section 1562 of the 1954 Code was repealed by section 401(a)(2) of the Tax Reform Act of 1969, Public Law 91–172, 83 Stat. 487 (December 30, 1969). The proposed regulations would remove from § 1.1502–1(f)(2) and (3) all references to section 1562 of the 1954 Code.

2. Section 1.1502–11 (Consolidated Taxable Income)

The proposed regulations would remove § 1.1502–11(a)(6), which provides that consolidated taxable income for a consolidated return year is determined by taking into account any ''consolidated section 922 deduction.'' Section 922 of the 1954 Code (providing a deduction for Western Hemisphere trade corporations) was repealed for taxable years beginning after December 31, 1979, by section 1052(b) of the Tax Reform Act of 1976, Public Law 94–455, 90 Stat. 1520 (October 4, 1976). In 1984, a subsequent section 922 (relating to foreign sales corporations) was added to the 1954 Code by section 801(a) of the Deficit Reduction Act of 1984, Public Law 98–369, 98 Stat. 494 (July 18, 1984), which defined the term ''FSC'' for purposes of statutory provisions regarding the taxation of foreign sales corporations. This subsequent section 922 of the 1954 Code was redesignated as section 922 of the Code (by section 2(a) of the Tax Reform Act of 1986, Pub. L. 99–514, 100 Stat. 2085 (October 22, 1986)) before its repeal by section 2 of

the FSC Repeal and Extraterritorial Income Exclusion Act of 2000, Public Law 106–519, 114 Stat. 2423 (November 15, 2000). This repeal applies to transactions after September 30, 2000. *See* section 5(a) of the FSC Repeal and Extraterritorial Income Exclusion Act of 2000.

The proposed regulations also would revise § 1.1502–11 to make other minor updates. Specifically, the proposed regulations would remove references to rules applicable to taxable years beginning before January 1, 1977, because those rules no longer have practical applicability to taxpayers. In addition, the proposed regulations would remove references to prior law regulations proposed to be withdrawn by this document.

3. Section 1.1502–12 (Separate Taxable Income)

The proposed regulations would remove § 1.1502–12(m), which provides that no deduction under now-repealed section 922 of the 1954 Code is taken into account in determining taxable income of separate corporations (that is, separate taxable income). *See* part II.A.2 of this Explanation of Provisions (describing the repeal of section 922 of the 1954 Code). The proposed regulations also would revise § 1.1502–12(n) to remove references to section 244 of the Code, which related to a special dividends-received deduction (DRD) for dividends received on certain preferred stock, and former section 247 of the Code, which related to a special DRD for dividends paid on certain preferred stock of public utilities. Sections 244 and 247 of the Code were repealed by section 221(a)(41)(A) of Division A of the Tax Increase Prevention Act of 2014, Public Law 113–295, 128 Stat. 4010 (December 19, 2014). Although section 13821(b)(1) of Public Law 115–97, 131 Stat. 2054 (December 22, 2017), commonly referred to as the ''Tax Cuts and Jobs Act'' (TCJA), added a new section 247 to the Code, that statutory provision allows deductions for certain contributions to Alaska Native Settlement Trusts and therefore is not applicable with regard to DRDs.

4. Section 1.1502–13 (Intercompany Transactions)

The proposed regulations would revise § 1.1502–13(c)(5) to remove a reference to section 595 of the Code, which provided nonrecognition treatment for foreclosure on property that secured the payment of indebtedness. Section 595 of the Code was repealed by section 1616(b)(8) of the Small Business Jobs Protection Act of 1996, Public Law 104–188, 110 Stat. 1755 (August 20, 1996).

5. Section 1.1502–24 (Consolidated Charitable Contributions Deduction)

Section 1.1502–24(a) sets forth a rule to determine the amount of the consolidated charitable contributions deduction for a consolidated group. The proposed regulations would revise § 1.1502–24(c) to remove the reference to section 242 of the 1954 Code, which allowed for a deduction for partially tax-exempt interest for C corporations. Section 242 of the 1954 Code was repealed by section 1901(a)(33) of the Tax Reform Act of 1976.

6. Section 1.1502–26 (Consolidated Dividends Received Deduction)

The proposed regulations would revise § 1.1502–26 by removing paragraphs (a)(2) through (6) of that section, which provide rules to calculate a consolidated DRD by taking into account thrift institution members of the group (including such members that compute a deduction based on the ''percentage of taxable income method'' under section 593(b)(2) of the Code). Section 1616(a) of the Small Business Jobs Protection Act of 1996 added section 593(f) to the Code. Section 593(f) provides that sections 593(a) through (d) of the Code do not apply to any taxable year beginning after December 31, 1995.

7. Section 1.1502–27 (Consolidated Section 247 Deduction) and Related Provisions

As discussed in part II.A.3 of this Explanation of Provisions, (i) section 247 of the Code was repealed by section 221(a)(41)(A) of Division A of the Tax Increase Prevention Act of 2014; and (ii) section 13821(b)(1) of the TCJA added to the Code a new section 247, which allows deductions for certain contributions to Alaska Native Settlement Trusts. Accordingly, the proposed regulations would remove § 1.1502–27, which provides rules under the version of section 247 of the Code repealed by the Tax Increase Prevention Act of 2014. The proposed regulations also would (i) remove § 1.1502–11(a)(8), which solely provides a reference to a consolidated section 247 deduction computed under § 1.1502–27, and (ii) revise §§ 1.1502–24(c) and 1.1502–43(b)(2)(iii), to remove a cross-reference to § 1.1502–27 in each respective section.

8. Section 1.1502–42 (Consolidated Returns Including Thrift Institutions) and Related Provisions

The proposed regulations would remove § 1.1502–42, which provides rules for members of a consolidated group that are thrift institutions (that is, any member that is described in section 593(a) of the Code). Section 1.1502–42 became obsolete as a result of the enactment of section 593(f) of the Code by section 1616(a) of the Small Business Jobs Protection Act of 1996, which provides that sections 593(a) through (d) of the Code do not apply to any taxable year beginning after December 31, 1995. The proposed regulations also would remove § 1.1502–12(q), which provides solely that a thrift institution's deduction under section 593(b)(2) of the Code is determined under § 1.1502–42.

9. Section 5.1502–45 (At-Risk Limitation Temporary Regulations)

The Treasury Department and the IRS published § 5.1502–45 as temporary regulations relating to the application of the at-risk limitations under section 465 of the 1954 Code to corporations that join with their subsidiaries in filing a consolidated return. *See* TD 7685, published in the **Federal Register** (45 FR 16484) on March 14, 1980 (at-risk limitation temporary regulations). Prior to the publication of § 5.1502–45, the Treasury Department determined that consolidated groups were actively considering transactions or plans to avoid the at-risk limitations. *See* preamble to the at-risk limitation temporary regulations, 45 FR 16484. Under the temporary regulations, if a parent meets the stock ownership test for a personal holding company, a subsidiary's loss from an activity to which section 465 of the Code (as redesignated by section 2(a) of the Tax Reform Act of 1986) applies will be allowed as a deduction on a consolidated return only to the extent that the parent is at risk in the activity of a subsidiary, under the principles of section 465 of the Code, as of the close of the subsidiary's taxable year. *See id.*

Section 5.1502–45(a)(4) refers to section 465(c)(3)(D) of the 1954 Code, which was repealed by section 503(a) of the Tax Reform Act of 1986. The Treasury Department and the IRS understand that no proposed regulations ever were published with regard to § 5.1502–45. Therefore, in addition to addressing the reference to repealed section 465(c)(3)(D) of the 1954 Code, this document proposes the entire text of § 5.1502–45 as proposed § 1.1502–45 and proposes to withdraw § 5.1502–45. The Treasury Department and the IRS request comments on proposed § 1.1502–45.

B. Updates To Reflect Amended Statutory Provisions

The proposed regulations would remove or revise regulations under section 1502 and other provisions of the Code that implement statutory provisions that have been substantially revised since those regulations were promulgated.

1. Section 1.167(c)–1 (Limitations on Methods of Computing Depreciation Under Section 167(b)(2), (3), and (4))

Section 1.167(c)–1(a)(5) provides a reference to certain provisions of the consolidated return regulations that address depreciation of property received by a member of an affiliated group from another member of the group during a consolidated return period. To implement amendments made by the TCJA to section 168(k) of the Code, the Department of the Treasury and the Internal Revenue Service published final regulations under § 1.1502–68 that provide guidance regarding the additional first-year depreciation deduction under section 168(k). *See* TD 9916, published in the **Federal Register** (85 FR 71734) on November 10, 2020. *See also* sections 12001(b)(13), 13201, and 13204 of the TCJA. Accordingly, the proposed regulations would revise § 1.167(c)–1(a)(5) to include a reference to § 1.1502–68.

2. Section 1.1502–1(g) (Definition of ''Consolidated Return Change of Ownership'')

The proposed regulations would remove paragraph (g) of § 1.1502–1, which provides rules to determine the occurrence of a consolidated return change of ownership (CRCO). The CRCO rules generally paralleled the ownership change rules of section 382 of the 1954 Code, as that section existed prior to enactment of the Tax Reform Act of 1986. *See* preamble to the NPRM published in the **Federal Register** (56 FR 4228, 4232) on February 4, 1991. Following the complete revision of section 382 of the 1954 Code by the Tax Reform Act of 1986, the Treasury Department and the IRS determined that the policies underlying the CRCO rules were subsumed by the single-entity approach to the application of section 382 of the Code to consolidated groups. *See* section 621(a) of the Tax Reform Act of 1986. *See also* 56 FR at 4232. Accordingly, the Treasury Department and the IRS replaced the CRCO rules with the consolidated section 382 rules set forth in §§ 1.1502–90 through 1.1502–99. *See* TD 8679, published in the **Federal Register** (61 FR 33313) on June 27, 1996.

3. Section 1.1502–3 (Consolidated Tax Credits)

The proposed regulations would remove § 1.1502–3(e), which applies only to a CRCO that occurred during a consolidated return year for which the due date of the Federal income tax return (without extensions) is on or before March 13, 1998. *See* § 1.1502–3(e)(3).

4. Section 1.1502–5 (Consolidated Estimated Tax)

The Treasury Department and the IRS published proposed regulations in the **Federal Register** (57 FR 62251) on December 30, 1992, regarding the computation of the former alternative minimum tax (Former AMT) by consolidated groups and the allocation of related items (consolidated Former AMT proposed regulations). The proposed regulations would incorporate in revised form part of the consolidated Former AMT proposed regulations that proposed to amend the consolidated estimated tax provisions in § 1.1502–5. The Treasury Department and the IRS received no comments on § 1.1502–5 as proposed in the consolidated Former AMT proposed regulations.

The proposed regulations would revise § 1.1502–5 to reflect the amendments to section 6655, which provides penalties for corporations failing to pay estimated income tax, made by section 10301(a) of the Omnibus Budget Reconciliation Act of 1987, Public Law 100–203, 101 Stat. 1330 (December 22, 1987). The proposed regulations also would remove references to section 6154 of the Code, which provided special rules for installment payments of estimated tax by corporations prior to the repeal of section 6154 of the Code by section 10301(b)(1) of the Omnibus Budget Reconciliation Act of 1987, and would add a reference to section 59A, which was added to section 6655(g)(1) by section 14401(d)(4)(A) of the TCJA.

The consolidated Former AMT proposed regulations provided guidance on consolidated estimated taxes under the Former AMT in section 55 of the Code and the environmental tax under former section 59A of the Code. The Former AMT was made inapplicable to corporations by section 12001(a) of the TCJA, and former section 59A of the Code was repealed by section 221(a)(12)(A), Division A, of the Tax Increase Prevention Act of 2014. Current section 59A of the Code (as added by section 14401(a) of the TCJA) imposes the base erosion and anti-abuse tax, commonly referred to as the ''BEAT.''

As a result of those amendments to the Code, the proposed regulations would make the following revisions to § 1.1502–5. First, the proposed regulations would not incorporate provisions from the consolidated Former AMT proposed regulations that addressed these issues. However, section 10101 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly referred to as the Inflation Reduction Act of 2022, amended section 55 of the Code to impose a new corporate alternative minimum tax based on adjusted financial statement income. This new corporate alternative minimum tax is commonly referred to as the corporate alternative minimum tax, or CAMT. Therefore, the proposed regulations would modify the definition of the term ''tax'' in § 1.1502–5(b)(5) to add a reference to section 55(a). In addition, the proposed regulations would add a reference to section 59A (that is, the BEAT).

The Treasury Department and the IRS are actively working on guidance to implement the CAMT, including guidance on the application of the CAMT to consolidated groups. Accordingly, issues regarding the substantive operation of the CAMT will be addressed in that guidance. However, these proposed regulations would provide guidance regarding the computation of consolidated estimated taxes to take into account the CAMT liability of the consolidated group.

5. Section 1.1502–9 (Consolidated Overall Foreign Losses, Separate Limitation Losses, and Overall Domestic Losses)

The proposed regulations would revise § 1.1502–9 to account for changes made by final foreign tax credit regulations (TD 9882) published in the **Federal Register** (84 FR 69022) on December 17, 2019. The final foreign tax credit regulations provide guidance relating to the determination of the foreign tax credit under the Code, implementing statutory changes made by the TCJA. In particular, the proposed regulations would revise § 1.1502–9 to remove references to the fair market value method option for interest expense apportionment, which was repealed by section 14502 of the TCJA. Relatedly, the proposed regulations would (1) update citations set forth in §§ 1.1502–9(a) and 1.1502–9(c)(2)(ii) and (iii), and (2) add a reference to § 1.861–13. In addition, the proposed regulations would update an internal cross-reference in § 1.1502–9(b)(1).

6. Section 1.1502–12(g) (Deductions Under Section 167 of the 1954 Code) and Related Provisions

Section 1.1502–12(g) was added to the consolidated return regulations by final regulations (TD 7246) published in the **Federal Register** (38 FR 758) on January 4, 1973. Section 1.1502–12(g) provides that, in the computation of the deduction under section 167 of the 1954 Code, property does not lose its character as new property as a result of a transfer from one member to another member during a consolidated return year if certain conditions are satisfied. Since the date of those final regulations, extensive changes to the depreciation rules of the Code have made § 1.1502–12(g) obsolete. *See, for example,* section 201 of the Economic Recovery Tax Act of 1981, Public Law 97–34, 95 Stat. 172 (August 13, 1981) (enacting section 168 of the 1954 Code, which provided the accelerated cost recovery system); section 201(a) of the Tax Reform Act of 1986 (amending section 168 of the Code, as redesignated by section 2(a) of the Tax Reform Act of 1986, to replace generally the accelerated cost recovery system with the modified accelerated cost recovery system).

As a result of the obsolescence of § 1.1502–12(g) due to the above-described enacted legislation, the proposed regulations would remove that provision. Relatedly, the proposed regulations would revise §§ 1.57–1(b)(4)(ii) and 1.167(c)–1(a)(5) to remove cross-references to § 1.1502–12(g). The proposed regulations also would remove the second sentence of § 1.1502–17(a), which refers the reader to § 1.1502–12(g) for the treatment of depreciable property after a transfer within the group.

7. Section 1.1502–24 (Consolidated Charitable Contributions Deduction)

As noted in part II.A.5 of this Explanation of Provisions, § 1.1502–24(a) sets forth a rule to determine the amount of the consolidated charitable contributions deduction for a group. Section 1.1502–24(a)(2) includes a reference to ''five percent'' of the adjusted consolidated taxable income of a group, which is based on section 170(b)(2) of the 1954 Code, as that section existed prior to enactment of the Economic Recovery Tax Act of 1981. Section 263(a) of the Economic Recovery Tax Act of 1981 amended section 170(b)(2) of the 1954 Code to increase the deduction limitation for corporations from 5 percent of the taxpayer's total income for a taxable year to 10 percent of that income.

The proposed regulations would revise § 1.1502–24(a)(2) to replace the reference to ''five percent'' with a reference to the ''percentage limitation on the total charitable contribution deduction provided in section 170(b)(2)(A).'' The Treasury Department and the IRS have proposed this revision, as opposed to a reference to ''10 percent'' (as currently set forth in section 170(b)(2)(A) of the Code), to reduce the need to provide future statutory updates to § 1.1502–24. *See* paragraph 9 of the Proposed Amendments to the Regulations, set forth in the NPRM (REG–101652–10) published in the **Federal Register** (80 FR 33211) on June 11, 2015.

8. Section 1.1502–26 (Consolidated Dividends Received Deduction)

Section 1.1502–26 provides rules for determining the consolidated DRD for the taxable year of a group. On several occasions since the publication of the original version of § 1.1502–26 in 1966, Congress has enacted legislation that amended the corporate DRD sections of the 1954 Code and the Code—most recently by section 13002 of the TCJA. To update § 1.1502–26 to reflect the corporate DRD provisions of the Code, the proposed regulations would revise § 1.1502–26(a) to replace the reference to the 85-percent DRD (reflecting the rate set forth in section 246(b)(1) of the 1954 Code, prior to the enactment of section 611(a)(3) of the Tax Reform Act of 1986) with a reference to the limitation on the aggregate amount of dividends-received deductions described in section 246(b) of the Code.

In addition, the proposed regulations would strike the reference to section 244 of the Code in § 1.1502–26(a), and the reference to section 247 of the Code in § 1.1502–26(b), both of which were repealed by section 221(a)(41)(A) of Division A of the Tax Increase Prevention Act of 2014. The proposed regulations also would revise the examples in § 1.1502–26(c) to reflect the updates made to § 1.1502–26.

9. Section 1.1502–34 (Special Aggregate Stock Ownership Rules)

Section 1.1502–34 provides that, for purposes of §§ 1.1502–1 through 1.1502–80, in determining the stock ownership of a member of a group in another corporation (issuing corporation) for purposes of determining the application of now-repealed section 333(b) of the 1954 Code, section 165(g)(3)(A) of the Code, section 332(b)(1) of the Code, section 351(a) of the Code, section 732(f) of the Code, or section 904(f) of the Code, in a consolidated return year, there is included stock owned by all other members of the group in the issuing corporation. Section 1.1502–34 also provides that the special rule for minority shareholders in now-repealed section 337(d) of the 1954 Code does not apply with respect to amounts received by applicable member shareholders in a liquidation of the issuing member.

Numerous statutory amendments have impacted the provisions described in § 1.1502–34. First, section 333 of the 1954 Code was repealed by section 631(e)(3) of the Tax Reform Act of 1986. In addition, section 631(a) of the Tax Reform Act of 1986 struck section 337 of the 1954 Code and replaced that provision with section 337 of the Code, which sets forth a subsection (d) that provides the Secretary with authority to prescribe regulations that are necessary or appropriate to carry out the purposes of *General Utilities* repeal. Lastly, section 337(c) of the Code was amended by section 10223(a) of title X of the Omnibus Budget Reconciliation Act of 1987 to clarify that, for purposes of section 337 of the Code, ''the determination of whether any corporation is an 80-percent distributee shall be made without regard to any consolidated return regulation.''

The proposed regulations would revise § 1.1502–34 to reflect those statutory amendments. Specifically, the proposed regulations would revise § 1.1502–34 to remove references to sections 333 and 337(d) of the 1954 Code. To reduce the need for future updates, the proposed regulations also would replace the reference to ''§§ 1.1502–1 through 1.1502–80'' with a reference to ''the consolidated return regulations,'' as defined in proposed § 1.1502–1(g). *See* part II.D.1 of this Explanation of Provisions.

10. Section 1.1502–79(d) (Carryover and Carryback of Consolidated Unused Foreign Tax)

Section 1.1502–79(d) provides rules addressing the apportionment of carryover and carryback of consolidated unused foreign tax to separate return years. The proposed regulations would update § 1.1502–79 to reflect changes to the foreign tax credit rules enacted since the regulation was issued as part of the 1966 final consolidated return regulations (TD 6894), published in the **Federal Register** (31 FR 11794) on September 8, 1966.

Specifically, the proposed regulations would revise § 1.1502–79(d) to remove references to the per-country foreign tax credit limitation that was repealed by section 1031(a) of the Tax Reform Act of 1976, update citations from section 904(d) to section 904(c) to reflect amendments to the 1954 Code made by section 1031(a) of the Tax Reform Act of

1976, and update a cross-reference from § 1.1502–4(e) to § 1.1502–4(d) to reflect the revision of § 1.1502–4 made by final regulations (TD 9922) published in the **Federal Register** (85 FR 71998) on November 12, 2020.

11. Section 1.1552–1 (Earnings and Profits of Members of Consolidated Groups)

Section 1.1552–1 requires generally that, for purposes of determining the earnings and profits of each member of an affiliated group that is required to be included in a consolidated return for the group filed for a taxable year beginning after December 31, 1953, and ending after August 16, 1954, the tax liability of the group is allocated among the members of the group in accordance with certain elected methods under § 1.1552–1(c). *See* § 1.1552–1(a). Currently, § 1.1552–1(a)(2)(ii)(*i*) contains references to a corporate surtax exemption.

However, section 301(a) of the Revenue Act of 1978, Public Law 95–600, 92 Stat. 2763 (November 6, 1978), struck section 11 of the 1954 Code and replaced that section with a new section 11 of the 1954 Code, which set forth a corporate income tax rather than a corporate surtax. Accordingly, the proposed regulations would revise § 1.1552–1(a)(2)(ii)(*i*) to remove the reference to the repealed corporate surtax.

12. Section 1.1563–1 (Controlled Group of Corporations and Component Members)

Section 1563(a) and 1.1563–1 define the term ''controlled group of corporations'' for purposes of sections 1561 through 1563 of the Code as including a ''parent-subsidiary controlled group.'' Section 1563(a)(1) defines a parent-subsidiary controlled group. In this regard, section 1563(d)(1) provides rules for determining stock ownership for purposes of determining whether a corporation is a member of a parent-subsidiary controlled group of corporations within the meaning of section 1563(a)(1). Section 1.1563–1(a)(2) incorporates these rules in defining a parent-subsidiary controlled group.

Prior to amendment by the Technical and Miscellaneous Revenue Act of 1988, Public Law 100–647, 102 Stat. 3342 (November 10, 1988), section 1563(d)(1) of the Code provided that for purposes of determining whether a corporation is a member of a parent-subsidiary controlled group of corporations, stock owned by a corporation means (A) stock owned directly by such corporation, and (B) stock owned with the application of section 1563(e)(1), which provides constructive ownership rules related to options to acquire stock. Similarly, § 1.1563–1(a)(2)(i)(A) and (B) provide that ownership of stock for purposes of determining a parent-subsidiary controlled group takes into account stock owned ''(directly and with the application of § 1.1563–3(b)(1), relating to options).''

Section 1018(s)(3)(A) of the Technical and Miscellaneous Revenue Act of 1988 amended section 1563(d)(1)(B) to expand the application of the constructive ownership rules of section 1563(e) for purposes of section 1563(d)(1) to include the constructive ownership rules of section 1563(e)(2) relating to attribution from partnerships and section 1563(e)(3) relating to attribution from estates or trusts. Accordingly, the proposed regulations would revise § 1.1563–1(a)(2)(i)(A) and (B) to include references to the constructive stock ownership rules in § 1.1563–3(b)(2) that attribute ownership of stock directly or indirectly owned by or for a partnership and the constructive stock ownership rules in § 1.1563–3(b)(3) that attribute ownership of stock directly or indirectly owned by or for an estate or trust, to conform with the statutory amendment to section 1563(d)(1)(B).

C. Removal of Non-Applicable Consolidated Return Regulations; Revisions To Remove Obsolete or Outdated References or Terms

The proposed regulations would remove numerous Treasury regulations that are obsolete because they no longer are applicable under their stated effective or applicability dates. In addition, the proposed regulations would revise numerous Treasury regulations that contain references or terms that have no practical applicability to taxpayers because they are, for example, obsoleted or otherwise outdated. Further, the proposed regulations would replace all gender-specific pronouns and other identifiers in the consolidated return regulations with gender-neutral pronouns and identifiers.

1. The ''Cap A'' Consolidated Return Regulations

Certain consolidated return regulations are designated with an ''A'' in the citation (for example, § 1.1502–9A). These regulations (Cap A regulations) generally are applicable only to taxable years ending in 1999 or earlier. The Cap A regulations provide rules regarding overall foreign loss recapture (§ 1.1502–9A), built-in deductions (§ 1.1502–15A), consolidated net operating losses (§ 1.1502–21A), consolidated capital gain or loss (§§ 1.1502–22A and 1.1502–41A), consolidated net ''section 1231'' gain or loss (§ 1.1502–23A), the agent for the group (§ 1.1502–77A), separate return years (§ 1.1502–79A), and the application of section 382 of the Code (§§ 1.1502–90A through 1.1502–99A).

The Cap A regulations have been superseded, in their entirety, by §§ 1.1502–9, 1.1502–15, 1.1502–21 through 1.1502–23, 1.1502–77, 1.1502–79, and 1.1502–90 through 1.1502–99. Therefore, with one exception, the proposed regulations would remove the Cap A regulations.

The proposed regulations would not remove § 1.1502–77A because that section has continuing applicability with regard to IRS examination and audit functions. Specifically, the IRS examination function has ongoing audits in which the years at issue are subject to the agent for the group rules in § 1.1502–77A. Because those rules address threshold issues including which entity may act on behalf of the group, and thus the validity of any filing by the group, § 1.1502–77A continues to have practical applicability for taxpayers.

The proposed regulations also would make conforming revisions to the consolidated return regulations due to the near-total removal of the Cap A regulations. For example, the proposed regulations would revise §§ 1.1502–11, 1.1502–43, and 1.1502–44 to remove all cross-references to the Cap A regulations. The proposed regulations also would revise § 1.382–8 (relating to controlled groups) to remove § 1.382–8(i), which provides references to the Cap A regulations.

2. Section 1.1502–13 (Intercompany Transactions)

The proposed regulations would revise § 1.1502–13 to remove outdated transition rules and references. Specifically, the proposed regulations would (i) revise § 1.1502–13(a)(3)(i) to remove a transition rule for consolidated return years beginning on or after November 7, 2001; (ii) revise § 1.1502–13(f)(5)(ii)(B)(*2*) to remove cross-references to obsolete temporary regulations that affected certain liquidations where the original Federal income tax return for the year of liquidation was filed on or before November 3, 2009; and (iii) revise § 1.1502–13(f)(6)(v) to remove references to transactions occurring before July 12, 1995.

3. Section 1.1502–17 (Methods of Accounting)

Section 1.1502–17 provides generally that the method of accounting to be used by each member of the group must be determined in accordance with the provisions of section 446 of the Code as if such member filed a separate return. *See* § 1.1502–17(a). Section 1.1502–17(e) refers taxpayers to § 1.1502–17 (as contained in the 26 CFR part 1 edition revised as of April 1, 1995) for changes in method of accounting effective for years beginning before July 12, 1995. The proposed regulations would revise § 1.1502–17(e) to strike that language because it has no practical applicability to taxpayers.

4. Section 1.1502–18 (Inventory Adjustment)

Section 1.1502–18 provides that, if a member of a group filing a consolidated return for the taxable year (i) was a member of the group for its immediately preceding taxable year, and (ii) filed a separate return for that preceding year, then the intercompany profit amount of that corporation for that separate return year (that is, the initial inventory amount) is added to the income of that corporation for the consolidated return year or years in which the goods to which the initial inventory amount is attributable are disposed of outside the group or that corporation becomes a non-member. *See* § 1.1502–18(b). Section 1.1502–18(a) provides that, for purposes of § 1.1502–18 and subject to certain exceptions, the term ''intercompany profit amount'' for a taxable year means an amount equal to the profits of a corporation arising in transactions with other members of the group with respect to goods that are, at the close of such corporation's taxable year, included in the inventories of any member of the group. *See* § 1.1502–18(a).

However, paragraphs (a) through (f) of § 1.1502–18 do not apply for taxable years beginning on or after July 12, 1995. *See* § 1.1502–18(g). Therefore, the special rules set forth in § 1.1502–18 have no practical applicability to taxpayers.

As a result, the proposed regulations would remove § 1.1502–18 and make conforming revisions to other Treasury regulations. With regard to such conforming revisions, the proposed regulations would remove § 1.279–6(d)(4), which provides that members of an affiliated group that file a consolidated return must not apply the provisions of § 1.1502–18 dealing with inventory adjustments in determining earnings and profits for purposes of § 1.279–6. The proposed regulations also would remove § 1.1502–12(e), which requires that, in computing the separate taxable income of a member, inventory adjustments must be made as provided in § 1.1502–18.

5. Section 1.1502–21 (Net Operating Losses)

Section 1.1502–21(b)(3)(i) and (ii) provide rules for consolidated groups to make irrevocable elections to relinquish certain carryback periods with regard to consolidated net operating losses. Elections under each of § 1.1502–21(b)(3)(i) and (ii) must be made through statements filed pursuant to rules set forth in those provisions. Each provision provides that, if the consolidated return year in which the loss arises begins before January 1, 2003, the statement making the election must be signed by the common parent. The proposed regulations would revise § 1.1502–21(b)(3)(i) and (b)(3)(ii)(B) to remove those special instructions regarding elections for pre-2003 taxable years because those special rules no longer have practical applicability to taxpayers.

The proposed regulations also would remove § 1.1502–21(d), which provides coordination rules for CRCOs that occurred before January 1, 1997. *See* part II.B.2 of this Explanation of Provisions (describing the replacement of the CRCO rules with the consolidated section 382 rules set forth in §§ 1.1502–90 through 1.1502–99).

6. Section 1.1502–22 (Consolidated Capital Gain and Loss)

Section 1.1502–22 provides generally that determinations under section 1222 (including capital gain and loss) with respect to members during consolidated return years are not made separately; rather, consolidated amounts are determined for the group as a whole. *See* § 1.1502–22(a). The proposed regulations would remove § 1.1502–22(d), which provides coordination rules for CRCOs that occurred before January 1, 1997. *See* part II.B.2 of this Explanation of Provisions.

7. Section 1.1502–24 (Consolidated Charitable Contributions Deduction)

The proposed regulations would revise § 1.1502–24(c) to remove the reference to § 1.1502–25, which provided rules for groups to compute a ''consolidated section 922 deduction.'' *See* part II.A.2 of this Explanation of Provisions (describing the repeal of section 922 of the 1954 Code by the Tax Reform Act of 1976). Section 1.1502–25 was removed by final regulations (TD 8474) published in the **Federal Register** (58 FR 25556) on April 27, 1993, which removed final and temporary regulations relating primarily to provisions of prior law in accordance with the Regulatory Burden Reduction Initiative of the Treasury Department and the IRS.

8. Section 1.1502–75 (Filing of Consolidated Returns)

Section 1.1502–75(h)(2) provides that, if a group wishes to file a consolidated return for a taxable year, then a Form 1122, *Authorization and Consent of Subsidiary Corporation To Be Included in a Consolidated Income Tax Return,* must be executed by each subsidiary. Section 1.1502–75(h)(2) also provides that, (i) for taxable years beginning after December 31, 2002, the group must attach either executed Forms 1122 or unsigned copies of the completed Forms 1122 to the consolidated return; but (ii) for taxable years beginning before January 1, 2003, the executed Forms 1122 must be attached to the consolidated return for the taxable year. This transition rule for taxable years beginning before January 1, 2003, no longer has practical applicability to taxpayers. Therefore, the proposed regulations would revise § 1.1502–75(h)(2) to provide simply that the group must attach either executed Forms 1122 or unsigned copies of the completed Forms 1122 to the consolidated return.

9. Section 1.1502–76 (Taxable Year of Members of Group)

Section 1.1502–76 sets forth rules for the taxable year of members of a group. The proposed regulations would revise § 1.1502–76(b)(1)(ii)(A)(*2*) and (b)(2)(v) to remove references to transactions occurring before November 10, 1999, because those references have no practical applicability to taxpayers.

10. Section 1.1502–80 (Applicability of Other Provisions of Law)

Section 1.1502–80 provides generally that (i) the Code, or other law, is applicable to the group to the extent the consolidated return regulations do not exclude its application; and (ii) to the extent not excluded, other rules operate in addition to, and may be modified by, the regulations. *See* § 1.1502–80(a)(1). Section 1.1502–80(c)(2) provides a cross-reference to § 1.1502–36 for additional rules relating to worthlessness of subsidiary stock on or after September 17, 2008. The proposed regulations would remove the reference to that date because it no longer has practical applicability to taxpayers.

Section 1.1502–80 also sets forth a special rule that provides that section

357(c) of the Code does not apply to any transaction to which § 1.1502–13 and other specified sections of the consolidated return regulations apply. *See* § 1.1502–80(d).

A concern arose in response to this rule that, because § 1.1502–80(d) provides that section 357(c) of the Code does not apply to certain intragroup section 351 exchanges, no liabilities can technically be excluded under section 357(c)(3). *See* preamble to proposed regulations (REG–137519–01) published in the **Federal Register** (66 FR 57021, 57022) on November 14, 2001 (proposed consolidated section 357(c) regulations). Therefore, in such an intragroup section 351 exchange, the transferor's basis in the stock of the transferee received in the transfer first would be reduced by liabilities assumed by the transferee, including those liabilities described in section 357(c)(3) of the Code that would not have reduced basis had section 357(c) applied. *See id.* Then, the transferor's basis in the stock of the transferee would be reduced a second time under the principles of § 1.1502–32 at the time the liability does in fact give rise to a deduction on the part of the transferee and is taken into account on the consolidated return. *See id.* This result ultimately could cause the transferor to recognize an amount of gain on the sale of the stock of the transferee that does not clearly reflect income. *See id.*

The Treasury Department and the IRS published the proposed consolidated section 357(c) regulations to eliminate potential duplicative stock basis reductions arising from such transactions. Specifically, those proposed regulations were published to clarify that, in certain transfers described in section 351 of the Code between members of a consolidated group, a transferee's assumption of liabilities described in section 357(c)(3)(A) of the Code, other than those also described in section 357(c)(3)(B) of the Code, will not reduce the transferor's basis in the transferee's stock received in the exchange. *See* Explanation of Provisions to the proposed consolidated section 357(c) regulations, 66 FR 57021.

However, upon reflection, the proposed rule is unnecessary because §§ 1.1502–32 and 1.1502–80 prevent any duplicative stock basis reduction. See § 1.1502–32(a)(2) (providing that a member's basis in its subsidiary's stock ''must not be adjusted under this section and other rules of law in a manner that has the effect of duplicating an adjustment.''); § 1.1502–80(a)(2) (''Nothing in these regulations shall be interpreted or applied to require an adjustment, inclusion, or other item to the extent it would have the effect of duplicating any other adjustment, inclusion, or other item required under the Code or other rule of law, including other provisions of these regulations.''). Accordingly, this document withdraws those proposed regulations.

11. Section 1.1502–81T (Alaska Native Corporations)

In 1984, Congress enacted legislation to revise the affiliation requirements under section 1504(a) of the 1954 Code to incorporate an 80-percent equity ownership test. *See* section 60(a) of the Deficit Reduction Act of 1984. However, the applicability of these statutory amendments was delayed until 1992 with respect to the affiliation of a corporation with an Alaska Native Corporation (ANC) established under the Alaska Native Claims Settlement Act, Public Law 92–203, 85 Stat. 688 (December 18, 1971). *See* section 60(b)(5) of the Deficit Reduction Act of 1984. Moreover, section 1804(e)(4) of the Tax Reform Act of 1986 struck section 60(b)(5) of the Deficit Reduction Act of 1984 and replaced that provision with a provision that, for any taxable year beginning after 1984 and before 1992, relaxed the requirements for affiliation with an ANC or with a wholly owned ANC subsidiary. Accordingly, until 1992, the pre-1984 affiliation requirements contained in section 1504(a) of the 1954 Code governed affiliation with an ANC or with a wholly owned ANC subsidiary, without regard to escrow arrangements, redemption rights, or similar provisions.

The Treasury Department and the IRS published temporary regulations to implement those statutory provisions (ANC temporary regulations). *See* TD 8130, published in the **Federal Register** (52 FR 8447) on March 18, 1987. Specifically, § 1.1502–81T makes clear that the statutory ANC affiliation rules resulted in no tax saving, tax benefit, or tax loss to any person, other than the use of the losses and credits of an ANC and its wholly owned subsidiaries. *See* preamble to the ANC temporary regulations (52 FR 8447).

In particular, the ANC temporary regulations provided that, except as approved by the Secretary, no positive adjustment under § 1.1502–32(b)(1) would be made with respect to the basis of stock of a corporation that is affiliated with an ANC through application of the ANC affiliation rules. *Id.* In general, such approval by the Secretary took into account the economic effect of the investment by the ANC in the corporation with which it is so affiliated. *Id.* The proposed regulations propose to withdraw § 1.1502–81T because those special affiliation rules no longer have practical applicability to taxpayers.

12. Section 1.1502–99 (Effective/Applicability Dates Regarding Consolidated Return Regulations Addressing Sections 382 and 383 of the Code)

The application of sections 382 and 383 of the Code in a consolidated return is addressed in §§ 1.1502–90 through 1.1502–99. In particular, § 1.1502–99 provides effective and applicability dates and transition rules for §§ 1.1502–90 through 1.1502–99. The proposed regulations would revise § 1.1502–99 to remove transition rules for testing periods that include June 25, 1999. Those transition rules have no practical applicability to taxpayers because taxable years subject to those transition rules generally are closed.

13. Section 1.1552–1 (Earnings and Profits)

Section 1.1552–1(a)(1)(ii) provides that the taxable income of a member is the separate taxable income determined under § 1.1502–12, adjusted for certain items taken into account in the computation of consolidated taxable income. One item, set forth in § 1.1552–1(a)(1)(ii)(B), is the ''member's capital gain net income (net capital gain for taxable years beginning before January 1, 1977) (determined without regard to any net capital loss carryover attributable to such member).'' The proposed regulations would revise § 1.1552–1(a)(1)(ii)(B) to remove the reference to net capital gain for taxable years beginning before January 1, 1977, because the reference to that date has no practical applicability to taxpayers.

14. Sections 1.1503–2 (Dual Consolidated Loss) and 1.1503(d)–8 (Effective Dates)

Section 1.1503–2 provides rules to address dual consolidated losses incurred in taxable years beginning on or after October 1, 1992, and before April 18, 2007 (or January 1, 2007, in limited instances). *See* § 1.1503–2(h) (providing October 1, 1992, applicability date) § 1.1503(d)–8 (providing April 18, 2007, and January 1, 2007, applicability dates). Dual consolidated losses incurred on or after April 18, 2007, or January 1, 2007, are subject to the rules set forth in §§ 1.1503(d)–1 through 1.1503(d)–7. *See* § 1.1503(d)–8. Therefore, the proposed regulations would remove § 1.1503–2 because that section has no practical applicability to taxpayers. For the same reason, the proposed regulations also

would make conforming changes to the effective date provisions set forth in § 1.1503(d)–8 to reflect the removal of § 1.1503–2.

15. Removal of Obsolete or Gendered Terminology

The proposed regulations would make nonsubstantive changes to the consolidated return regulations to removed obsolete or gendered terminology the proposed regulations would replace all gender-specific pronouns and other identifiers in the consolidated return regulations with gender-neutral pronouns and identifiers. *See* part I of this Explanation of Provisions. The proposed regulations would replace the term ''possession'' with the defined term ''U.S. territory'' in §§ 1.1502–4(d)(1) and 1.1503(d)–1(b)(7). *See* proposed § 1.1502–1(l). The proposed regulations also would replace all gender-specific pronouns and other identifiers in the consolidated return regulations and the regulations under section 1563 of the Code with gender-neutral pronouns and identifiers.

D. Changes To Improve Clarity

The proposed regulations would make various revisions to the consolidated return regulations that are intended to increase their clarity and usability. These proposed revisions are limited to creating defined terms, updating cross-references, correcting numbering, and other minor, non-substantive edits.

1. Section 1.1502–1 (Definitions)

Currently, the regulations under section 1502 of the Code reference the term ''consolidated return regulations'' in several provisions, although that term is not defined in those regulations. In addition, certain provisions in the regulations published under section 1502 of the Code refer to multiple sections of the regulations. At the time of publication, those provisions were intended to refer to all regulations under section 1502. However, due to the publication of additional regulations under section 1502 of the Code, those references are no longer accurate. To avoid taxpayer confusion, the proposed regulations would add a defined term ''consolidated return regulations'' to § 1.1502–1 that would not need to be updated to account for future additions to the regulations under section 1502 of the Code. *See* proposed § 1.1502–1(g).

2. Section 1.1502–13(f)(7) (Examples Regarding Intercompany Transactions With Respect to Stock of Members)

As part of final regulations (TD 9475) addressing corporate reorganizations and distributions under sections 368(a)(1)(D) and 354(b)(1)(B) of the Code, published in the **Federal Register** (74 FR 67053) on December 18, 2009, the Treasury Department and the IRS inserted a new *Example 4* into the intercompany transaction examples set forth in § 1.1502–13(f)(7). However, those final regulations did not update internal cross-references to certain existing examples in § 1.1502–13(f)(7), which were redesignated as a result of new *Example 4.* Accordingly, the proposed regulations would revise § 1.1502–13(f)(7) to update those internal cross-references. More generally, the proposed regulations would add paragraph designations to undesignated examples throughout § 1.1502–13.

3. Section 1.1502–32(b)(4) and (5) (Waiver of Loss Carryovers From Separate Return Limitation Years and Examples)

The proposed regulations would revise § 1.1502–32(b)(4) to remove paragraphs that cross-reference provisions of the loss disallowance regulations under § 1.1502–20 that were removed by final regulations (TD 9424) published in the **Federal Register** (73 FR 53934) on September 17, 2008 (final unified loss regulations). Section 1.1502–20 provided loss-disallowance rules with regard to the disposition or deconsolidation of subsidiary stock. As provided in the preamble to the final unified loss regulations, the Treasury Department and the IRS do not expect that § 1.1502–20 would affect any transactions occurring on or after September 17, 2008 (the applicability date of those final regulations). *See* 73 FR 53944. The proposed regulations would replace the removed paragraphs with cross-references to provisions set forth in § 1.1502–32(b)(4), as contained in 26 CFR part 1, revised as of April 1, 2005.

Additionally, the proposed regulations would correct an error in *Example 6* of § 1.1502–32(b)(5)(ii), which (1) addressed an intercompany reorganization described in section 368(a)(1)(A) of the Code (and in section 368(a)(1)(D) of the Code), and (2) treats a receipt of $10 of boot as a dividend under section 356(a)(2) of the Code. This treatment of intercompany boot conflicts with § 1.1502–13(f)(3)(ii), which expressly provides that nonqualifying property (that is, money or other property) received as part of such intercompany reorganization (that is, a transaction to which section 354 of the Code would apply but for the fact that nonqualifying property is received) is treated as received by the member shareholder in a separate transaction occurring immediately after the transaction.

4. Section 1.1502–47 (Consolidated Returns by Life-Nonlife Groups)

The proposed regulations would revise § 1.1502–47(b), (h), and (j) to correct certain typographical errors and update certain cross-references.

5. Section 1.1502–75 (Filing of Consolidated Returns)

The proposed regulations would revise § 1.1502–75(c)(1) to set forth the current procedures for a group to request to discontinue filing consolidated returns. The proposed regulations would remove § 1.1502–75(d)(5), which applies to consolidated return years in which an existing consolidated group obtains a new common parent solely by reason of the enactment of section 833 of the Code as part of the Tax Reform Act of 1986. This provision no longer has practical applicability to taxpayers. In addition, the proposed regulations would update § 1.1502–75(h)(1) to reflect final regulations (TD 9715) that revise rules regarding agency for consolidated groups under § 1.1502–77, which were published in the **Federal Register** (80 FR 17314) on April 1, 2015. The proposed regulations also would update § 1.1502–75(h)(1) to reflect the elimination of the district director positions by the Commissioner pursuant to section 1001 of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206, 112 Stat. 685 (July 22, 1998).

6. Section 1.1502–76 (Taxable Year of Members of Group)

The proposed regulations would revise § 1.1502–76(a) to set forth the current procedures for taxpayers requesting consent of the Commissioner if at least one member of the group is on a 52–53-week taxable year and all members of the group have taxable years ending within the same 7-day period. The proposed regulations also would revise several examples in §§ 1.1502–76(c)(3) and 1.1502–77(g) to reflect changes to the due date for Federal corporate income tax returns set forth in section 6072(a) of the Code, as made by section 2006(a)(2) of the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015, Public Law 114–41, 129 Stat. 443 (July 31, 2015).

7. Section 1.1502–79 (Separate Return Years)

Section 1.1502–79(e)(2) provides a rule to determine the portion of the consolidated excess charitable

contributions attributable to a member of a consolidated group. The proposed regulations would make non-substantive changes to enhance the clarity of that provision. In particular, the proposed regulations would separate the current one-sentence rule into three sentences, the first of which provides that the portion of the consolidated excess charitable contributions for any year attributable to a member is an amount equal to the consolidated excess contributions multiplied by a fraction. The second and third sentences set forth the numerator and denominator of that fraction, respectively.

8. Section 1.1502–100 (Corporations Exempt From Tax)

Section 1.1502–100 provides rules to compute the tax liability for a consolidated return year of a group of exempt corporations that files or is required to file a consolidated return for the taxable year. The proposed regulations would revise § 1.1502–100(a)(2) to replace the reference to ''§§ 1.1502–1 through 1.1502–80'' with a reference to ''the consolidated return regulations'' (*see* the discussion in parts II.B.9 and II.D.1 of this Explanation of Provisions.) The proposed regulations also would revise § 1.1502–100(d) to reflect the changes proposed by this document to § 1.1502–12.

9. Removal of Cross-References to Prior-Law Versions of the CFR

In general, the proposed regulations would revise numerous provisions in the consolidated return regulations to remove cross-references to prior-law versions of the CFR. However, the proposed regulations would retain cross-references in the consolidated return regulations to prior-law CFRs with continuing relevance. In particular, the proposed regulations would retain cross-references relating to intercompany transactions and certain separate return limitation year issues.

E. Provisions Affected by Legislation That the Proposed Regulations Do Not Change

The proposed regulations would not modify certain provisions in the consolidated return regulations that have been affected by subsequent legislation. Principally, aside from the nonsubstantive change discussed in part II.B.3 of this Explanation of Provisions, the proposed regulations would not revise § 1.1502–3 (relating to consolidated credits). Section 1.1502–3 provides rules for the former investment tax credit that existed prior to its replacement by the general business credit in section 211 of the Tax Reform Act of 1986. The proposed regulations also would not revise § 1.1502–79(c), which provides rules for the carryover and carryback of unused investment credits to separate return years. Because of extensive changes to the relevant statutory provisions, substantive revisions of §§ 1.1502–3 and 1.1502–79(c) are beyond the scope of these proposed regulations. However, the Treasury Department and the IRS are considering updating §§ 1.1502–3 and 1.1502–79(c) to reflect current law, and the Treasury Department and the IRS request comments on potential revisions to these regulatory provisions.

F. Withdrawal of Proposed Regulations; Proposed Withdrawal of Temporary Regulations

1. Notices of Proposed Rulemaking Incorporated Into the Proposed Regulations or Into Final Regulations

This document withdraws the portions of two NPRMs that, in revised form, (i) have been incorporated into final regulations, or (ii) are incorporated into these proposed regulations in revised form.

a. Consolidated Former Alternative Minimum Tax Proposed Regulations

As discussed in part II.B.4 of this Explanation of Provisions, the Treasury Department and the IRS published the consolidated Former AMT proposed regulations on December 30, 1992, regarding the computation of the Former AMT by consolidated groups and the allocation of related items. This document withdraws proposed amendments to § 1.1502–2, regarding the computation of a consolidated group's tax liability, set forth in the consolidated Former AMT proposed regulations. These proposed amendments were incorporated, in revised form, into the base erosion and anti-abuse tax final regulations (TD 9885), published in the **Federal Register** (84 FR 66968) on December 6, 2019 (BEAT final regulations). However, the proposed amendments to § 1.1502–2 set forth in the consolidated Former AMT proposed regulations were not withdrawn by the BEAT final regulations. Accordingly, this document withdraws the revisions to § 1.1502–2 proposed by the consolidated Former AMT proposed regulations.

The consolidated Former AMT proposed regulations also would provide rules under § 1.1552–1(h) governing the allocation of the environmental tax imposed by section 59A of the Code (as in effect at the time) to members for purposes of computing earnings and profits. Section 59A of the Code was repealed by section 221(a)(12)(A), Division A, of the Tax Increase Prevention Act of 2014. As a result, this document withdraws proposed § 1.1552–1(h), as contained in the consolidated Former AMT proposed regulations.

b. Proposed Regulations Regarding Absorption of Members' Losses and To Eliminate Circular Basis Adjustments

The Treasury Department and the IRS published a NPRM (REG–101652–10) in the **Federal Register** (80 FR 33211) on June 11, 2015 (circular basis proposed regulations). The circular basis proposed regulations would provide guidance regarding the absorption of members' losses in a consolidated return year, and provide guidance to eliminate circular adjustments to the basis of a group member. These circular basis proposed regulations would have (i) revised §§ 1.1502–11(a) and 1.1502–24 to remove references to repealed statutes or obsolete regulations, and (ii) removed §§ 1.1502–21A, 1.1502–22A, and 1.1502–23A. Because this document would (i) make the same revisions to §§ 1.1502–11(a) and 1.1502–24, and (ii) remove §§ 1.1502–21A, 1.1502–22A, and 1.1502–23A, this document withdraws the proposed revisions to §§ 1.1502–11(a), 1.1502–21A, 1.1502–22A, 1.1502–23A, and 1.1502–24 set forth in the circular basis proposed regulations.

2. NPRM That Became Obsolete as a Result of Incorporation of Subsequent NPRM Into Final Regulations

On March 18, 2004, the Treasury Department and the IRS published in the **Federal Register** (69 FR 12811) a NPRM (REG–153172–03) under § 1.1502–80(c) (proposed loss limitation rules). The proposed loss limitation rules set forth guidance regarding (i) the deductibility of losses recognized on dispositions of subsidiary stock by members of a consolidated group, (ii) the consequences of treating subsidiary stock as worthless, and (iii) when stock of a member of a consolidated group may be treated as worthless. The proposed loss limitation rules cross-referenced temporary regulations (TD 9118) published in the **Federal Register** (69 FR 12799) on the same day, the text of which served as the text for those proposals.

On July 18, 2007, the Treasury Department and the IRS published in the **Federal Register** (72 FR 39313) final regulations (TD 9341), which finalized a version of § 1.1502–80(c) that had been proposed by an NPRM (REG–157711–02) published in the **Federal Register** (72 FR 2964) on January 23, 2007. Those

final regulations removed § 1.1502–80T(c) but did not withdraw the proposed loss limitation rules. Accordingly, this document withdraws the proposed loss limitation rules.

3. NPRMs That Cross-Reference Temporary Regulations That Have Been Removed, Have Expired, or Otherwise Have Become Obsolete

a. NPRMs Under § 1.1502–20

The Treasury Department and the IRS published four NPRMs under § 1.1502–20, which cross-referenced temporary regulations under § 1.1502–20T published in the **Federal Register** on the same day, the text of which served as the text for those proposals. On September 17, 2008, the Treasury Department and the IRS published final regulations (TD 9424) in the **Federal Register** (73 FR 53934) that included the final unified loss rule under § 1.1502–36. As a result of these final regulations, the Treasury Department and the IRS removed §§ 1.1502–20 and 1.1502–20T. However, the four NPRMs under § 1.1502–20 were not withdrawn by those final regulations.

Accordingly, this document withdraws the four NPRMs under § 1.1502–20, which consist of the following:

(1) An NPRM (REG–102740–02) published in the **Federal Register** (67 FR 11070) on March 12, 2002, which cross-referenced the text of temporary regulations (TD 8984) published in the **Federal Register** (67 FR 11034) on the same day (March 12 unified loss proposed regulations).

(2) An NPRM (REG–102305–02) published in the **Federal Register** (67 FR 38040) on May 31, 2002, which clarified and revised aspects of the March 12 unified loss proposed regulations and cross-referenced the text of temporary regulations (TD 8998) published in the **Federal Register** (67 FR 37998) on the same day.

(3) An NPRM (REG–152524–02) published in the **Federal Register** (68 FR 24404) on May 7, 2003, which cross-referenced the text of temporary regulations (TD 9057) published in the **Federal Register** (68 FR 24351) on the same day.

(4) An NPRM (REG–135898–04) published in the **Federal Register** (69 FR 52462) on August 26, 2004, which cross-referenced the text of temporary regulations (TD 9154) published in the **Federal Register** (69 FR 52419) on the same day.

b. NPRMs Under § 1.1502–21

The Treasury Department and the IRS published three NPRMs under § 1.1502–21, which cross-referenced temporary regulations under § 1.1502–21T published in the **Federal Register** on the same day, the text of which served as the text for those proposals. These NPRMs also contained proposed regulations under § 1.1502–32 (*see* part II.F.3.c of this Explanation of Provisions).

Each of these temporary regulations under § 1.1502–21T has expired or has been removed. However, the Treasury Department and the IRS have not yet withdrawn the three NPRMs under § 1.1502–21.

Accordingly, this document withdraws three NPRMs under § 1.1502–21, which consist of the following:

(1) An NPRM (REG–122564–02) published in the **Federal Register** (67 FR 38039) on May 31, 2002, which addressed elections for consolidated groups to waive the carryback of certain losses arising in 2001 or 2002 and cross-referenced the text of temporary regulations (TD 8997) published in the **Federal Register** (67 FR 38000) on the same day.

(2) An NPRM (REG–131478–02) published in the **Federal Register** (68 FR 12324) on March 14, 2003, which addressed losses treated as expired under § 1.1502–35T(f)(1) on and after March 7, 2002, and on or before March 11, 2006 (including corresponding basis adjustments), and cross-referenced the text of temporary regulations (TD 9048) published in the **Federal Register** (68 FR 12287) on the same day.

(3) An NPRM (REG–151605–09) published in the **Federal Register** (75 FR 35710) on June 23, 2010, which addressed elections by consolidated groups to elect to extend a net operating loss carryback period arising in a single taxable year ending after December 31, 2007, and beginning before January 1, 2010, and cross-referenced the text of now-expired temporary regulations (TD 9490) published in the **Federal Register** (75 FR 35643) on the same day.

c. NPRMs Under § 1.1502–32

The Treasury Department and the IRS published five NPRMs under § 1.1502–32 that cross-referenced temporary regulations under § 1.1502–32T published in the **Federal Register** on the same day, the text of which served as the text for those proposals. Each of these temporary regulations under § 1.1502–32T has expired or have been removed. However, the Treasury Department and the IRS have not yet withdrawn the corresponding five NPRMs under § 1.1502–32.

Accordingly, this document withdraws the five NPRMs under § 1.1502–32, which consist of the following:

(1) An NPRM (REG–129274–04) published in the **Federal Register** (69 FR 51208) on August 18, 2004, which addressed elections for consolidated groups to waive the carryback of certain losses arising in 2001 or 2002 and cross-referenced the text of temporary regulations (TD 9155) published in the **Federal Register** (69 FR 51175) on the same day.

(2) An NPRM (REG–156420–06) published in the **Federal Register** (72 FR 17814) on April 10, 2007 (proposed anti-avoidance and anti-loss reimportation regulations), which proposed an anti-avoidance rule and revised an anti-loss reimportation rule, and cross-referenced the text of temporary regulations (TD 9322) published in the **Federal Register** (72 FR 17804) on the same day. The proposed anti-avoidance and anti-loss importation regulations also contained proposed regulations under § 1.1502–35 (*see* part II.F.3.d of this Explanation of Provisions).

(3) Each NPRM described in part II.F.3.b of this Explanation of Provisions.

d. NPRM Under § 1.1502–35

The Treasury Department and the IRS published two NPRMs under § 1.1502–35, which cross-referenced temporary regulations under § 1.1502–35T published in the **Federal Register** on the same day, the text of which served as the text for those proposals. The temporary regulations under § 1.1502–35T have expired or have been removed. However, the Treasury Department and the IRS have not yet withdrawn the corresponding two NPRMs under § 1.1502–35.

Accordingly, this document withdraws the two NPRMs under § 1.1502–35, which consist of the following:

(1) An NPRM (REG 153172–03) published in the **Federal Register** (69 FR 12811) on March 18, 2004, which proposed guidance regarding worthless subsidiary stock, and cross-referenced the text of temporary regulations (TD 9118) published in the **Federal Register** (69 FR 12799) on the same day.

(2) The proposed anti-avoidance and anti-loss reimportation regulations, described in part II.F.3.c of this Explanation of Provisions.

Proposed Applicability Date

Pursuant to section 1503(a) of the Code, these proposed regulations would apply to consolidated return years for which the due date of the return (without regard to extensions) is after

the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Special Analyses

I. Regulatory Planning and Review

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

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

These regulations update the regulations under section 1502 of the Code (that is, the consolidated return regulations) by revising and removing outdated and obsolete provisions, such as cross-references to temporary regulations, regulations, and statutes that have been repealed, removed, expired, renumbered, or otherwise have become obsolete. Therefore, the proposed regulations would not impose additional reporting burden beyond what is otherwise required by existing statutes, regulations, and forms. The total burden associated with the proposed regulations, if finalized in their current form, would be $0.

III. Regulatory Flexibility Act

The proposed regulations would not impose a collection of information on small entities. Further, pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that the proposed regulations would not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the proposed regulations would apply only to corporations that file consolidated Federal income tax returns, and that such corporations tend to be larger businesses. Therefore, the proposed regulations would not create additional obligations for, or impose an economic impact on, small entities.

Pursuant to section 7805(f) of the Code, the proposed regulations have been submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $190 million. The proposed regulations do not propose any rule that would include any Federal mandate that may result in expenditures by State, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. The proposed regulations do not propose rules that would have federalism implications, impose substantial direct compliance costs on State and local governments, or preempt State law within the meaning of the Executive order.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations, including comments on any consolidated return rules not addressed in these proposed regulations that require revision or removal as a result of amendments to the Code or regulations made after such rules were promulgated. All commenters are strongly encouraged to submit comments electronically. The Treasury Department and the IRS will publish for public availability any comment submitted electronically or on paper to its public docket on *https://www.regulations.gov.*

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing are encouraged to be made electronically. If a public hearing is scheduled, a notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2023–16, 2023–20 IRB 854, provides that, following the end of the national emergency concerning the Coronavirus Disease 2019 (COVID–19) pandemic, the IRS no longer will conduct public hearings on notices of proposed rulemaking solely by telephone for proposed regulations published in the **Federal Register** after May 11, 2023. A telephonic option will remain available for those who prefer to attend or testify at a public hearing by telephone. Any telephonic hearing will be made accessible to people with disabilities.

Statement of Availability of IRS Documents

Announcement 2023–16, 2023–20 IRB 854, is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

Drafting Information

The principal authors of this document are Kelton P. Frye and William W. Burhop of the Office of Associate Chief Counsel (Corporate). Other personnel from the Treasury Department and the IRS participated in its development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 5

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR parts 1, 5, 301, and 602 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the

entries for §§ 1.1503–2, 1.1502–9A, 1.1502–15A, 1.1502–21A, 1.1502–22A, 1.1502–23A, 1.1502–41A, 1.1502–79A, 1.1502–91A, 1.1502–92A, 1.1502–93A, 1.1502–94A, 1.1502–95A, 1.1502–96A, 1.1502–98A, and 1.1502–99A to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.57–1 [Amended]

■ **Par. 2.** Section 1.57–1 is amended by removing the text ''and § 1.1502–12(g)'' from paragraph (b)(4)(ii).

■ **Par. 3.** Section 1.167(c)–1 is amended by revising paragraph (a)(5) to read as follows:

§ 1.167(c)–1 Limitations on methods of computing depreciation under section 167(b)(2), (3), and (4).

(a) * * *

(5) See §§ 1.1502–13 and 1.1502–68 for provisions dealing with depreciation of property received by a member of an affiliated group from another member of the group during a consolidated return period.

* * * * *

§ 1.279–6 [Amended]

■ **Par. 4.** Section 1.279–6 is amended by:

■ 1. Removing the text ''and'' from the end of paragraph (d)(1).

■ 2. Adding the text ''and'' to the end of paragraph (d)(2).

■ 3. Removing the text '', and'' from the end of paragraph (d)(3) and adding the text ''.'' in its place.

■ 4. Removing paragraph (d)(4).

§ 1.382–8 [Amended]

■ **Par. 5.** Section 1.382–8 is amended by removing and reserving paragraph (i).

■ **Par. 6.** Section 1.1502–0 is revised to read as follows:

§ 1.1502–0 Effective/Applicability dates.

(a) *In general.* Except as provided in paragraph (b) of this section, the consolidated return regulations (as defined in § 1.1502–1(g)) are applicable to taxable years beginning after December 31, 1965.

(b) *Exceptions.* The applicability date described in paragraph (a) of this section does not apply to any provision of the consolidated return regulations with an applicability or effective date different than the date provided by paragraph (a) of this section.

■ **Par. 7.** Section 1.1502–1 is amended by:

■ 1. Adding introductory text.

■ 2. Removing the text '','' from the end of paragraph (f)(2)(iii) and adding the text ''.'' in its place.

■ 3. Removing the undesignated paragraph after paragraph (f)(2)(iii).

■ 4. Removing the text ''and for which section 1562 was not effective'' from the last sentence of paragraph (f)(3).

■ 5. Revising paragraph (g).

■ 6. Redesignating paragraph (l) as paragraph (m).

■ 7. Adding a new paragraph (l).

The revision and addition read as follows:

§ 1.1502–1 Definitions.

For purposes of the consolidated return regulations:

* * * * *

(g) *Consolidated return regulations.* The term *consolidated return regulations* means the regulations under section 1502.

* * * * *

(l) *U.S. territory.* The *term U.S. territory* means—

(1) American Samoa;

(2) The Commonwealth of the Northern Mariana Islands;

(3) The Commonwealth of Puerto Rico;

(4) Guam; and

(5) The Virgin Islands of the United States.

* * * * *

§ 1.1502–3 [Amended]

■ **Par. 8.** Section 1.1502–3 is amended by removing and reserving paragraph (e).

§ 1.1502–4 [Amended]

■ **Par. 9.** Section 1.1502–4 is amended by removing the text ''possession'' from paragraph (d)(1) and adding the text ''U.S. territory'' in its place.

■ **Par. 10.** Section 1.1502–5 is revised to read as follows:

§ 1.1502–5 Estimated tax.

(a) *General rule*—(1) *Consolidated estimated tax.* If a group files a consolidated return for two consecutive taxable years, it must make payments of estimated tax on a consolidated basis for each subsequent taxable year until separate returns are filed. When filing on a consolidated basis, the group is generally treated as a single corporation for purposes of section 6655 (relating to payment of estimated tax by corporations). If separate returns are filed by the members for a taxable year, the amount of any estimated tax payments made with respect to a consolidated estimated tax for the year is credited against the separate tax liabilities of the members in any reasonable manner designated by the common parent.

(2) *First two consolidated return years.* For its first two consolidated return years, a group may make payments of estimated tax on either a consolidated or a separate member basis. The amount of any separate estimated tax payments is credited against the consolidated tax liability of the group.

(b) *Addition to tax for failure to pay estimated tax under section 6655*—(1) *Consolidated return filed.* For its first two consolidated return years, a group may compute the amount of the penalty (if any) under section 6655 on a consolidated basis or a separate member basis, regardless of the method of payment. Thereafter, the group must compute the penalty for any consolidated return year on a consolidated basis.

(2) *Computation of penalty on consolidated basis.* (i) This paragraph (b)(2) provides rules for computing the penalty under section 6655 on a consolidated basis.

(ii) The tax shown on the return for the preceding taxable year referred to in section 6655(d)(1)(B)(ii) is, if a consolidated return was filed for that preceding year, the tax shown on the consolidated return for that preceding year or, if a consolidated return was not filed for that preceding year, the aggregate of the taxes shown on the separate returns of the common parent and any other corporation that was a member of the same affiliated group as the common parent for that preceding year.

(iii) If estimated tax was not paid on a consolidated basis, the amount of the group's payments of estimated tax for the taxable year is the aggregate of the payments made by all members for the year.

(iv) If the common parent is otherwise eligible to use the section 6655(d)(1)(B)(ii) required annual payment rule, that rule applies only if the group's consolidated return, or each member's separate return if the group did not file a consolidated return, for the preceding taxable year was a taxable year of 12 months.

(3) *Computation of penalty on separate member basis.* To compute any penalty under section 6655 on a separate member basis, for purposes of section 6655(d)(1)(B)(i), the ''tax shown on the return'' for the taxable year is the portion of the tax shown on the consolidated return allocable to the member under paragraph (b)(6) of this section. If the member was included in the consolidated return filed by the group for the preceding taxable year, for purposes of section 6655(d)(1)(B)(ii), the ''tax shown on the return'' for the preceding taxable year for any member is the portion of the tax shown on the consolidated return for the preceding

year allocable to the member under paragraph (b)(6) of this section.

(4) *Consolidated payments if separate returns filed.* If the group does not file a consolidated return for the taxable year but makes payments of estimated tax on a consolidated basis, for purposes of section 6655(b)(1)(B), the ''amount (if any) of the installment paid'' by any member is an amount apportioned to the member in any reasonable manner designated by the common parent. If a member was included in the consolidated return filed by the group for the preceding taxable year, the amount of the member's penalty under section 6655 is computed on the separate member basis described in paragraph (b)(3) of this section.

(5) *Tax defined.* For purposes of this section, the term ''tax'' means the excess of—

(i) The sum of—

(A) The consolidated tax imposed by section 11 or subchapter L of chapter 1, whichever applies;

(B) The tax imposed by section 55(a); plus

(C) The tax imposed by section 59A; over

(ii) The credits against tax provided by part IV of subchapter A of chapter 1 of the Internal Revenue Code.

(6) *Allocation of consolidated tax liability for determining earnings and profits.* For purposes of this section, the tax shown on a consolidated return is allocated to the members of the group by allocating any tax described in paragraph (b)(5)(i) of this section, net of allowable credits under paragraph (b)(5)(ii) of this section, under the method that the group has elected pursuant to section 1552 and § 1.1502–33(d).

(c) *Examples.* The provisions of this section are illustrated by the following examples.

(1) *Example 1.* Corporations P and S1 file a consolidated return for the first time for calendar year 2021. P and S1 also file consolidated returns for calendar year 2022 and calendar year 2023. Under paragraph (a)(2) of this section, for the 2021 and 2022 taxable years, P and S1 may pay estimated tax on either a separate or consolidated basis. Under paragraph (a)(1) of this section, for the 2023 taxable year, the group must pay its estimated tax on a consolidated basis. In determining whether P and S1 come within the exception provided in section 6655(d)(1)(B)(ii) for 2023, the ''tax shown on the return'' is the tax shown on the consolidated return for the 2022 taxable year.

(2) *Example 2.* Corporations P, S1, and S2 file a consolidated return for the first time for calendar year 2021 and file their second consolidated return for calendar year 2022. S2 ceases to be a member of the group on September 15, 2023. Under paragraph (b)(2) of this section, in determining whether the group (which no longer includes S2) comes within the exception provided in section 6655(d)(1)(B)(ii) for 2023, the ''tax shown on the return'' is the tax shown on the consolidated return for calendar year 2022.

(3) *Example 3.* Corporations P and S1 file a consolidated return for the first time for calendar year 2021 and file their second consolidated return for calendar year 2022. Corporation S2 becomes a member of the group on July 1, 2023, and joins in the filing of the consolidated return for calendar year 2023. Under paragraph (b)(2) of this section, in determining whether the group (which now includes S2) comes within the exception provided in section 6655(d)(1)(B)(ii) for 2023, the ''tax shown on the return'' is the tax shown on the consolidated return for calendar year 2022. Any tax of S2 for any separate return year is not included as a part of the ''tax shown on the return'' for purposes of applying section 6655(d)(1)(B)(ii).

(4) *Example 4.* Corporations X and Y file consolidated returns for the calendar years 2021 and 2022 and separate returns for calendar year 2023. Under paragraph (b)(3) of this section, in determining whether X or Y comes within the exception provided in section 6655(d)(1)(B)(ii) for 2023, the ''tax shown on the return'' is the amount of tax shown on the consolidated return for 2022 allocable to X and to Y in accordance with paragraph (b)(6) of this section.

(d) *Cross-references*—(1) For provisions relating to quick refunds of corporate estimated tax payments, see §§ 1.1502–78 and 1.6425–1 through 1.6425–3.

(2) For provisions relating to depositing estimated taxes, see § 1.6302–1(b).

(e) *Applicability date.* This section applies to any taxable year for which the due date of the income tax return (without regard to extensions) is on or after [the date final regulations are published in the **Federal Register**]. For prior years, see § 1.1502–5 (as contained in the 26 CFR edition revised as of April 1, 2023).

§ 1.1502–6 [Amended]

■ **Par. 11.** Section 1.1502–6 is amended by removing the text ''he'' from paragraph (b) and adding the text ''the Commissioner'' in its place.

■ **Par. 12.** Section 1.1502–9 is amended by:

■ 1. Removing the text ''§ 1.904–4(m)'' from paragraph (a) and adding the text ''§ 1.904–5(a)(4)(v)'' in its place.

■ 2. Removing the text ''(a)(8)'' from the first sentence of paragraph (b)(1) and adding the text ''(a)(6)'' in its place.

■ 3. Removing the text ''§§ 1.861–9T(g)(3) and 1.861–12T'' from the second sentence of paragraph (c)(2)(ii) and adding the text ''§§ 1.861–9T(g)(3), 1.861–12, and 1.861–13'' in its place.

■ 4. Removing the text ''§ 1.861–9T(g)(1)'' from paragraph (c)(2)(ii) wherever it appears and adding the text ''§ 1.861–9(g)(1)'' in its place.

■ 5. Removing the text '', fair market value,'' from the sixth sentence of paragraph (c)(2)(ii).

■ 6. Removing the text ''§ 1.861–9T(g)(2))'' from paragraph (c)(2)(ii) wherever it appears and adding the text ''§ 1.861–9(g)(2))'' in its place.

■ 7. Removing the text ''If the group uses the tax book value method, the'' from the eighth sentence of paragraph (c)(2)(ii) and adding the text ''The'' in its place.

■ 8. Revising the heading of paragraph (c)(2)(iii).

■ 9. Removing the text ''a group uses the tax book value method of valuing assets for purposes of paragraph (c)(2)(ii) of this section and'' from the first sentence of paragraph (c)(2)(iii).

§ 1.1502–9 Consolidated overall foreign losses, separate limitation losses, and overall domestic losses.

* * * * *

(c) * * *

(2) * * *

(iii) *Limitation on member's portion.*

* * *

* * * * * *

■ **Par. 13.** Section 1.1502–11 is amended by:

■ 1. Revising the introductory text in paragraph (a).

■ 2. Revising paragraphs (a)(2) through (4).

■ 3. Adding the text ''and'' at the end of paragraph (a)(5).

■ 4. Removing paragraph (a)(6).

■ 5. Redesignating paragraph (a)(7) as paragraph (a)(6).

■ 6. In newly redesignated paragraph (a)(6), removing the text ''; and'', and adding the text ''.'' in its place.

■ 7. Removing paragraph (a)(8).

■ 8. In paragraph (b)(2)(iii), designating *Examples 1* through *3* as paragraphs (b)(2)(iii)(A) through (C), respectively.

■ 9. In newly redesignated paragraphs (b)(2)(iii)(A) through (C), further redesignating the paragraphs in the first column as the paragraphs in the second column:

Old paragraphs	New paragraphs
(b)(2)(iii)(A)(a), (b), and (c)	(b)(2)(iii)(A)(*1*), (*2*), and (*3*).
(b)(2)(iii)(B)(a), (b), (c), and (d)	(b)(2)(iii)(B)(*1*), (*2*), (*3*), and (*4*).
(b)(2)(iii)(C)(a), (b), (c), (d), and (e)	(b)(2)(iii)(C)(*1*), (*2*), (*3*), (*4*), and (*5*).

■ 10. Removing the text ''(or 1.1502–79A, as appropriate)'' from newly redesignated paragraphs (b)(2)(iii)(A)(*3*) and (b)(2)(iii)(B)(*4*).

■ 11. Removing the last sentence of paragraph (c)(7).

The revisions read as follows:

§ 1.1502–11 Consolidated taxable income.

(a) *In general.* The consolidated taxable income (CTI) for a consolidated return year is determined by taking into account:

* * * * *

(2) Any consolidated net operating loss (CNOL) deduction (see § 1.1502–21 for the computation of the CNOL deduction);

(3) Any consolidated capital gain net income (see § 1.1502–22 for the computation of consolidated capital gain net income);

(4) Any consolidated section 1231 net loss (see § 1.1502–23 for the computation of consolidated section 1231 net loss);

* * * * *

■ **Par. 14.** Section 1.1502–12 is amended by:

■ 1. Revising paragraph (b).

■ 2. Removing and reserving paragraphs (e), (g), and (m).

■ 3. Revising paragraph (n).

■ 4. Removing and reserving paragraph (q).

The revisions read as follows:

§ 1.1502–12 Separate taxable income.

* * * * *

(b) Any deduction that is disallowed under § 1.1502–15 must be taken into account as provided in that section.

* * * * *

(n) No deduction under section 243(a)(1) or section 245 (relating to deductions with respect to dividends received) is taken into account;

* * * * *

■ **Par. 15.** Section 1.1502–13 is amended by:

■ 1. Revising the second sentence of paragraph (a)(3)(i).

■ 2. Revising paragraph (a)(6)(ii).

■ 3. Adding the text ''of this section'' after the text ''paragraph (c)(4)(i)(A)'' in the first sentence of paragraph (c)(4)(i)(B).

■ 4. Revising the last sentence of paragraph (c)(5).

■ 5. In paragraph (d)(3), designating *Examples 1* through *5* as paragraphs (d)(3)(i) through (v), respectively.

■ 6. In newly redesignated paragraphs (d)(3)(i) through (v), further redesignating paragraphs in the first column as paragraphs in the second column:

Old paragraphs	New paragraphs
(d)(3)(i)(a), (b), (c), (d), (e), (f), and (g)	(d)(3)(i)(A), (B), (C), (D), (E), (F), and (G).
(d)(3)(ii)(a), (b), and (c)	(d)(3)(ii)(A), (B), and (C).
(d)(3)(iii)(a) and (b)	(d)(3)(iii)(A) and (B).
(d)(3)(iv)(a), (b), and (c)	(d)(3)(iv)(A), (B), and (C).
(d)(3)(v)(a) and (b)	(d)(3)(v)(A) and (B).

■ 7. In paragraph (d)(3), for each newly redesignated paragraph listed in the ''Paragraph'' column, removing the text indicated in the ''Remove'' column and adding in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(d)(3)(i)(E)	paragraph (a) of this *Example 1*	paragraph (d)(3)(i)(A) of this section (*Example 1*).
(d)(3)(i)(F)	paragraph (a) of this *Example 1*	paragraph (d)(3)(i)(A) of this section (*Example 1*).
(d)(3)(i)(G)	paragraph (a) of this *Example 1*	paragraph (d)(3)(i)(A) of this section (*Example 1*).
(d)(3)(ii)(C)	paragraph (a) of this *Example 2*	paragraph (d)(3)(ii)(A) of this section (*Example 2*).

■ 8. In paragraph (e)(1)(v), designating *Examples 1* through *3* as paragraphs (e)(1)(v)(A) through (C), respectively.

■ 9. In newly redesignated paragraphs (e)(1)(v)(A) through (C), further redesignating paragraphs in the first column as paragraphs in the second column:

Old paragraphs	New paragraphs
(e)(1)(v)(A)(a), (b), (c)(i), (c)(ii), (d), and (e)	(e)(1)(v)(A)(*1*), (*2*), (*3*)(*i*), (*3*)(*ii*), (*4*), and (*5*).
(e)(1)(v)(B)(a), (b)(i), (b)(ii), and (c)	(e)(1)(v)(B)(*1*), (*2*)(*i*), (*2*)(*ii*), and (*3*).
(e)(1)(v)(C)(a) and (b)	(e)(1)(v)(C)(*1*) and (*2*).

■ 10. In paragraph (e)(1)(v), for each newly redesignated paragraph listed in the ''Paragraph'' column, removing the text indicated in the ''Remove'' column and adding in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(e)(1)(v)(A)(*4*)	paragraph (a) of this *Example 1*	paragraph (e)(1)(v)(A)(*1*) of this section (*Example 1*).
(e)(1)(v)(A)(*5*)	paragraph (a) of this *Example 1*	paragraph (e)(1)(v)(A)(*1*) of this section (*Example 1*).
(e)(1)(v)(B)(*1*)	*Example 1*	paragraph (e)(1)(v)(A)(*1*) of this section (*Example 1*).

Paragraph	Remove	Add
(e)(1)(v)(B)(*3*)	paragraph (a) of this *Example 2*	paragraph (e)(1)(v)(B)(*1*) of this section (*Example 2*).

■ 11. Removing the second sentence from paragraph (f)(5)(ii)(B)(*2*).
■ 12. Removing the text ''In either case, the'' from the third sentence of paragraph (f)(5)(ii)(B)(*2*) and adding the text ''The'' in its place.
■ 13. Revising paragraph (f)(5)(ii)(F).
■ 14. Revising paragraphs (f)(6)(ii) and (v).
■ 15. In paragraph (f)(7), designating *Examples 1* through *7* as paragraphs (f)(7)(i) through (vii), respectively.
■ 16. In newly redesignated paragraphs (f)(7)(i) through (vii), further redesignating paragraphs in the first column as paragraphs in the second column:

Old paragraphs	New paragraphs
(f)(7)(i)(a), (b), (c), (d), and (e)	(f)(7)(i)(A), (B),(C), (D), and (E).
(f)(7)(ii)(a), (b), (c), (d), (e), (f), and (g)	(f)(7)(ii)(A), (B), (C), (D), (E), (F), and (G).
(f)(7)(iii)(a), (b), (c), and (d)	(f)(7)(iii)(A), (B), (C), and (D).
(f)(7)(iv)(a) and (b)	(f)(7)(iv)(A) and (B).
(f)(7)(v)(a), (b), (c), and (d)	(f)(7)(v)(A), (B), (C), and (D).
(f)(7)(vi)(a), (b), and (c)	(f)(7)(vi)(A), (B), and (C).
(f)(7)(vii)(a), (b), (c), and (d)	(f)(7)(vii)(A), (B), (C), and (D).

■ 17. In paragraph (f)(7), for each newly redesignated paragraph listed in the ''Paragraph'' column, removing the text indicated in the ''Remove'' column and adding in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(f)(7)(i)(D)	paragraph (a) of this *Example 1*	paragraph (f)(7)(i)(A) of this section (*Example 1*).
(f)(7)(i)(E)	paragraph (a) of this *Example 1*	paragraph (f)(7)(i)(A) of this section (*Example 1*).
(f)(7)(ii)(D)	paragraph (a) of this *Example 2*	paragraph (f)(7)(ii)(A) of this section (*Example 2*).
(f)(7)(ii)(D)	paragraph (c) of this *Example 2*	paragraph (f)(7)(ii)(C) of this section (*Example 2*).
(f)(7)(ii)(E)	paragraph (a) of this *Example 2*	paragraph (f)(7)(ii)(A) of this section (*Example 2*).
(f)(7)(ii)(F)	paragraph (a) of this *Example 2*	paragraph (f)(7)(ii)(A) of this section (*Example 2*).
(f)(7)(ii)(F)	paragraph (c) of this *Example 2*	paragraph (f)(7)(ii)(C) of this section (*Example 2*).
(f)(7)(ii)(F)	paragraph (d) of this *Example 2*	paragraph (f)(7)(ii)(D) of this section (*Example 2*).
(f)(7)(ii)(G)	paragraph (a) of this *Example 2*	paragraph (f)(7)(ii)(A) of this section (*Example 2*).
(f)(7)(ii)(G)	paragraph (c) of this *Example 2*	paragraph (f)(7)(ii)(C) of this section (*Example 2*).
(f)(7)(iii)(C)	paragraph (a) of this *Example 3*	paragraph (f)(7)(iii)(A) of this section (*Example 3*).
(f)(7)(iii)(C)	paragraph (b) of this *Example 3*	paragraph (f)(7)(iii)(B) of this section (*Example 3*).
(f)(7)(v)(C)	paragraph (a) of this *Example 4*	paragraph (f)(7)(v)(A) of this section (*Example 5*).
(f)(7)(v)(C)	paragraph (b) of this *Example 4*	paragraph (f)(7)(v)(B) of this section (*Example 5*).
(f)(7)(v)(D)	paragraph (a) of this *Example 4*	paragraph (f)(7)(v)(A) of this section (*Example 5*).
(f)(7)(vi)(C)	paragraph (a) of this *Example 5*	paragraph (f)(7)(vi)(A) of this section (*Example 6*).
(f)(7)(vii)(C)	paragraph (a) of this *Example 6*	paragraph (f)(7)(vii)(A) of this section (*Example 7*).
(f)(7)(vii)(C)	paragraph (b) of this *Example 6*	paragraph (f)(7)(vii)(B) of this section (*Example 7*).
(f)(7)(vii)(D)	paragraph (c) of this *Example 6*	paragraph (f)(7)(vii)(C) of this section (*Example 7*).

■ 18. In paragraph (g)(7)(ii), designating *Examples 1* through *11* as paragraphs (g)(7)(ii)(A) through (K), respectively.
■ 19. In newly redesignated paragraphs (g)(7)(ii)(A) through (K), further redesignating paragraphs in the first column as paragraphs in the second column:

Old paragraphs	New paragraphs
(g)(7)(ii)(A)(i), (ii), (iii), and (iv)	(g)(7)(ii)(A)(*1*), (*2*), (*3*), and (*4*).
(g)(7)(ii)(B)(i), (ii), (iii), (iv), (v), (vi), (vii), and (viii)	(g)(7)(ii)(B)(*1*), (*2*), (*3*), (*4*), (*5*), (*6*), (*7*), and (*8*).
(g)(7)(ii)(C)(i), (ii), (iii), and (iv)	(g)(7)(ii)(C)(*1*), (*2*), (*3*), and (*4*).
(g)(7)(ii)(D)(i), (ii), (iii), (iv), and (v)	(g)(7)(ii)(D)(*1*), (*2*), (*3*), (*4*), and (*5*).
(g)(7)(ii)(E)(i) and (ii)	(g)(7)(ii)(E)(*1*) and (*2*).
(g)(7)(ii)(F)(i) and (ii)	(g)(7)(ii)(F)(*1*) and (*2*).
(g)(7)(ii)(G)(i) and (ii)	(g)(7)(ii)(G)(*1*) and (*2*).
(g)(7)(ii)(H)(i) and (ii)	(g)(7)(ii)(H)(*1*) and (*2*).
(g)(7)(ii)(I)(i) and (ii)	(g)(7)(ii)(I)(*1*) and (*2*).
(g)(7)(ii)(J)(i), (ii), (iii), and (iv)	(g)(7)(ii)(J)(*1*), (*2*), (*3*), and (*4*).
(g)(7)(ii)(K)(i), (ii), and (iii)	(g)(7)(ii)(K)(*1*), (*2*), and (*3*).

■ 20. In paragraph (g)(7)(ii), for each newly redesignated paragraph listed in the ''Paragraph'' column, removing the text indicated in the ''Remove'' column and adding in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(g)(7)(ii)(A)(*3*)	paragraph (i) of this *Example 1*	paragraph (g)(7)(ii)(A)(*1*) of this section (*Example 1*).
(g)(7)(ii)(A)(*3*)	paragraph (ii) of this *Example 1*	paragraph (g)(7)(ii)(A)(*2*) of this section (*Example 1*).
(g)(7)(ii)(A)(*4*)	paragraph (i) of this *Example 1*	paragraph (g)(7)(ii)(A)(*1*) of this section (*Example 1*).
(g)(7)(ii)(A)(*4*)	paragraph (ii) of this *Example 1*	paragraph (g)(7)(ii)(A)(*2*) of this section (*Example 1*).
(g)(7)(ii)(B)(*3*)	paragraph (i) of this *Example 2*	paragraph (g)(7)(ii)(B)(*1*) of this section (*Example 2*).
(g)(7)(ii)(B)(*3*)	paragraph (ii) of this *Example 2*	paragraph (g)(7)(ii)(B)(*2*) of this section (*Example 2*).
(g)(7)(ii)(B)(*4*)	paragraph (i) of this *Example 2*	paragraph (g)(7)(ii)(B)(*1*) of this section (*Example 2*).
(g)(7)(ii)(B)(*4*)	paragraph (iii) of this Example 2	paragraph (g)(7)(ii)(B)(*3*) of this section (*Example 2*).
(g)(7)(ii)(B)(*5*)	paragraph (i) of this *Example 2*	paragraph (g)(7)(ii)(B)(*1*) of this section (*Example 2*).
(g)(7)(ii)(B)(*6*)	same as paragraph (i) of this *Example 2*	same as in paragraph (g)(7)(ii)(B)(*1*) of this section (*Example 2*).
(g)(7)(ii)(B)(*6*)	paragraph (ii) of this *Example 2*	paragraph (g)(7)(ii)(B)(*2*) of this section (*Example 2*).
(g)(7)(ii)(B)(*7*)	paragraph (i) of this *Example 2*	paragraph (g)(7)(ii)(B)(*1*) of this section (*Example 2*).
(g)(7)(ii)(B)(*8*)	paragraph (i) of this *Example 2*	paragraph (g)(7)(ii)(B)(*1*) of this section (*Example 2*).
(g)(7)(ii)(C)(*3*)	paragraph (i) of this *Example 3*	paragraph (g)(7)(ii)(C)(*1*) of this section (*Example 3*).
(g)(7)(ii)(C)(*3*)	paragraph (ii) of this *Example 3*	paragraph (g)(7)(ii)(C)(*2*) of this section (*Example 3*).
(g)(7)(ii)(C)(*4*)	paragraph (i) of this *Example 3*	paragraph (g)(7)(ii)(C)(*1*) of this section (*Example 3*).
(g)(7)(ii)(C)(*4*)	paragraph (ii) of this *Example 3*	paragraph (g)(7)(ii)(C)(*2*) of this section (*Example 3*).
(g)(7)(ii)(C)(*4*)	paragraph (ii) of this *Example 3*	paragraph (g)(7)(ii)(C)(*2*) of this section (*Example 3*).
(g)(7)(ii)(D)(*3*)	paragraph (i) of this *Example 4*	paragraph (g)(7)(ii)(D)(*1*) of this section (*Example 4*).
(g)(7)(ii)(D)(*4*)	paragraph (i) of this *Example 4*	paragraph (g)(7)(ii)(D)(*1*) of this section (*Example 4*).
(g)(7)(ii)(D)(*5*)	paragraph (i) of this *Example 4*	paragraph (g)(7)(ii)(D)(*1*) of this section (*Example 4*).
(g)(7)(ii)(J)(*2*)	*paragraph (iii) of Example 1 of this paragraph (g)(7).*	paragraph (g)(7)(ii)(A)(*3*) of this section (*Example 1*).
(g)(7)(ii)(J)(*3*)	paragraph (i) of this *Example 10*	paragraph (g)(7)(ii)(J)(*1*) of this section (*Example 10*).
(g)(7)(ii)(K)(*3*)	paragraph (i) of this *Example 11*	paragraph (g)(7)(ii)(K)(*1*) of this section (*Example 11*).

■ 21. Redesignating paragraphs (h)(2)(v)(a) and (b) as paragraphs (h)(2)(v)(A) and (B).

■ 22. In paragraph (j)(9), designating *Examples 1* through *7* as paragraphs (j)(9)(i) through (vii), respectively.

■ 23. In newly redesignated paragraphs (j)(9)(i) through (vii), further redesignating paragraphs in the first column as paragraphs in the second column:

Old paragraphs	New paragraphs
(j)(9)(i)(a), (b), (c), (d), and (e)	(j)(9)(i)(A), (B), (C), (D), and (E).
(j)(9)(ii)(a) and (b)	(j)(9)(ii)(A) and (B).
(j)(9)(iii)(a), (b), and (c)	(j)(9)(iii)(A), (B), and (C).
(j)(9)(iv)(a), (b), (c), (d), and (e)	(j)(9)(iv)(A), (B), (C), (D), and (E).
(j)(9)(v)(a) and (b)	(j)(9)(v)(A) and (B).
(j)(9)(vi)(a) and (b)	(j)(9)(vi)(A) and (B).
(j)(9)(vii)(a) and (b)	(j)(9)(vii)(A) and (B).

■ 24. In paragraph (j)(9), for each newly redesignated paragraph listed in the ''Paragraph'' column, removing the text indicated in the ''Remove'' column and adding in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(j)(9)(i)(E)	paragraph (a) of this *Example 1*	paragraph (j)(9)(i)(A) of this section (*Example 1*).
(j)(9)(iv)(D)	paragraph (a) of this *Example 4*	paragraph (j)(9)(iv)(A) of this section (*Example 1*).
(j)(9)(iv)(E)	paragraph (a) of this *Example 4*	paragraph (j)(9)(iv)(A) of this section (*Example 1*).

■ 25. Revising paragraph (l)(6).

■ 26. Redesignating paragraph (m) as paragraph (l)(7).

■ 27. Revising newly redesignated paragraph (l)(7).

■ 28. Adding paragraphs (l)(8) and (9).

The revisions and additions read as follows:

§ 1.1502–13 Intercompany transactions.

(a) * * *

(3) * * *

(i) * * * See §§ 1.1502–17 and 1.446–1(c)(2)(iii). * * *

* * * * *

(6) * * *

(ii) *Table of examples.* This section contains the following examples:

Rule	General location	Paragraph	Example
(A) Matching rule	§ 1.1502–13(c)(7)(ii)	(A)	Example 1. Intercompany sale of land followed by sale to a non-member.
		(B)	Example 2. Dealer activities.
		(C)	Example 3. Intercompany section 351 transfer.
		(D)	Example 4. Depreciable property.
		(E)	Example 5. Intercompany sale followed by installment sale.

Rule	General location	Paragraph	Example
		(F)	Example 6. Intercompany sale of installment obligation.
		(G)	Example 7. Performance of services.
		(H)	Example 8. Rental of property.
		(I)	Example 9. Intercompany sale of a partnership interest.
		(J)	Example 10. Net operating losses subject to section 382 or the SRLY rules.
		(K)	Example 11. Section 475.
		(L)	Example 12. Section 1092.
		(M)	Example 13. [Reserved].
		(N)	Example 14. Source of income under section 863.
		(O)	Example 15. Section 1248.
		(P)	Example 16. Intercompany stock distribution followed by section 332 liquidation.
		(Q)	Example 17. Intercompany stock sale followed by section 355 distribution.
		(R)	Example 18. Redetermination of attributes for section 250 purposes.
(B) Acceleration rule	§ 1.1502–13(d)(3)	(i)	Example 1. Becoming a nonmember—timing.
		(ii)	Example 2. Becoming a nonmember—attributes.
		(iii)	Example 3. Selling member's disposition of installment note.
		(iv)	Example 4. Cancellation of debt and attribute reduction under section 108(b).
		(v)	Example 5. Section 481.
(C) Simplifying rules—inventory	§ 1.1502–13(e)(1)(v)	(A)	Example 1. Increment averaging method.
		(B)	Example 2. Increment valuation method.
		(C)	Example 3. Other reasonable inventory methods.
(D) Stock of members	§ 1.1502–13(f)(7)	(i)	Example 1. Dividend exclusion and property distribution.
		(ii)	Example 2. Excess loss accounts.
		(iii)	Example 3. Intercompany reorganization.
		(iv)	Example 4. All cash intercompany reorganization under section 368(a)(1)(D).
		(v)	Example 5. Stock redemptions and distributions.
		(vi)	Example 6. Intercompany stock sale followed by section 332 liquidation.
		(vii)	Example 7. Intercompany stock sale followed by section 355 distribution.
(E) Obligations of members	§ 1.1502–13(g)(7)(ii)	(A)	Example 1. Interest on intercompany obligation.
		(B)	Example 2. Intercompany obligation becomes nonintercompany obligation.
		(C)	Example 3. Loss or bad debt deduction with respect to intercompany obligation.
		(D)	Example 4. Intercompany nonrecognition transactions.
		(E)	Example 5. Assumption of intercompany obligation.
		(F)	Example 6. Extinguishment of intercompany obligation.
		(G)	Example 7. Exchange of intercompany obligations.
		(H)	Example 8. Tax benefit rule.
		(I)	Example 9. Issuance at off-market rate of interest.
		(J)	Example 10. Nonintercompany obligation becomes intercompany obligation.
		(K)	Example 11. Notional principal contracts.
(F) Anti-avoidance rules	§ 1.1502–13(h)(2)	(i)	Example 1. Sale of a partnership interest.
		(ii)	Example 2. Transitory status as an intercompany obligation.
		(iii)	Example 3. Corporate mixing bowl.
		(iv)	Example 4. Partnership mixing bowl.
		(v)	Example 5. Sale and leaseback.
		(vi)	Example 6. Section 163(j) interest limitation.
(G) Miscellaneous operating rules	§ 1.1502–13(j)(9)	(i)	Example 1. Intercompany sale followed by section 351 transfer to member.
		(ii)	Example 2. Intercompany sale of member stock followed by recapitalization.
		(iii)	Example 3. Back-to-back intercompany transactions—matching.
		(iv)	Example 4. Back-to-back intercompany transactions—acceleration.
		(v)	Example 5. Successor group.
		(vi)	Example 6. Liquidation—80% distributee.
		(vii)	Example 7. Liquidation—no 80% distributee.

* * * * *

(c) * * *

(5) * * * For other special status issues, see, for example, sections 818(b) (life insurance company treatment of capital gains and losses) and 1503(c) (limitation on absorption of certain losses).

* * * * *

(f) * * *

(5) * * *

(ii) * * *

(F) *Applicability date.* Paragraphs (f)(5)(ii)(B)(*1*) and (*2*) of this section apply to transactions in which old T's

liquidation into B occurs on or after October 25, 2007.

(6) * * *

(ii) *Gain stock.* For dispositions of P stock, see § 1.1032–3.

* * * * *

(v) *Applicability date.* This paragraph (f)(6) applies to gain or loss taken into account on or after July 12, 1995, and to transactions occurring on or after July 12, 1995.

* * * * *

(l) * * *

(6) *Applicability date regarding paragraph (f)(7)(iv) of this section (Example 4).* Paragraph (f)(7)(iv) of this section (*Example 4*) applies to transactions occurring on or after December 18, 2009.

(7) *Election to apply paragraph (f)(5)(ii) of this section to an intercompany transaction.* Paragraph (f)(5)(ii)(E) of this section applies to any original consolidated Federal income tax return due (without extensions) after June 14, 2007.

(8) *Election to reduce basis of parent stock under paragraph (f)(6) of this section.* Paragraph (f)(6)(i)(C)(*2*) of this section applies to any original consolidated Federal income tax return due (without extensions) after June 14, 2007.

(9) *Certain qualified stock dispositions.* Paragraph (f)(5)(ii)(C) of this section applies to any qualified stock disposition (as defined in § 1.336–1(b)(6)) for which the disposition date (as defined in § 1.336–1(b)(8)) is on or after May 15, 2013.

§ 1.1502–17 [Amended]

■ **Par. 16.** Section 1.1502–17 is amended by removing the last sentence of paragraph (a) and the second sentence of paragraph (e).

§ 1.1502–18 [Removed]

■ **Par. 17.** Section 1.1502–18 is removed.

■ **Par. 18.** Section 1.1502–21 is amended by:

■ 1. In paragraph (b)(3)(i), removing the fourth sentence and revising the last sentence.

■ 2. In paragraph (b)(4), removing the fifth sentence and revising the last sentence.

■ 3. Removing and reserving paragraph (d).

■ 4. Removing the last three sentences of paragraph (h)(6).

■ 5. Removing the second sentence of paragraph (h)(8).

The revisions read as follows:

§ 1.1502–21 Net operating losses.

* * * * *

(b) * * *

(3) * * *

(i) * * * The election may be made in an unsigned statement.

(ii) * * *

(B) * * * The election may be made in an unsigned statement.

* * * * *

§ 1.1502–22 [Amended]

■ **Par. 19.** Section 1.1502–22 is amended by removing and reserving paragraph (d).

■ **Par. 20.** Section 1.1502–24 is amended by:

■ 1. Revising paragraph (a)(2).

■ 2. Removing the text ''section 242, section 243(a)(2) and (3), § 1.1502–25, § 1.1502–26, and § 1.1502–27,'' from paragraph (c) and adding the text ''section 243(a)(2) and (3) and § 1.1502–26,'' in its place.

The revision reads as follows:

§ 1.1502–24 Consolidated charitable contributions deduction.

(a) * * *

(2) The percentage limitation on the total charitable contribution deduction provided in section 170(b)(2)(A) applied to adjusted consolidated income as determined under paragraph (c) of this section.

* * * * *

■ **Par. 21.** Section 1.1502–26 is amended by:

■ 1. Revising paragraph (a).

■ 2. Designating *Examples 1* and *2* in paragraph (c) as paragraphs (c)(1) and (2), respectively.

■ 3. Revising newly designated paragraphs (c)(1) and (2).

The revisions read as follows:

§ 1.1502–26 Consolidated dividends received deduction.

(a) *In general.* The consolidated dividends received deduction for the taxable year is the lesser of—

(1) The aggregate of the deduction of the members of the group allowable under sections 243(a)(1), 245(a) and (b), and 250 (computed without regard to the limitations provided in section 246(b)), or

(2) The aggregate amount described in section 246(b), determined by substituting, wherever it appears—

(i) The term *consolidated taxable income* for *taxable income,*

(ii) The term *consolidated net operating loss* for *net operating loss,* and

(iii) The term *consolidated net capital loss* for *capital loss.*

* * * * *

(c) * * *

(1) *Example 1.* Corporations P, S, and S–1 filed a consolidated return for the calendar year 2023 showing consolidated taxable income of $100,000 (determined without regard to the consolidated net operating loss deduction, and the consolidated dividends received deduction). These corporations received dividends during such year from less than 20-percent owned domestic corporations as follows:

TABLE 1 TO PARAGRAPH (c)(1)

Corporation	Dividends
P	$6,000
S	10,000
S–1	34,000
Total	50,000

The dividends received deduction allowable to each member under section 243(a)(1) (computed without regard to the limitation in section 246(b)) is as follows: P has $3,000 (50 percent of $6,000), S has $5,000 (50 percent of $10,000), and S–1 has $17,000 (50 percent of $34,000), or a total of $25,000. Since $25,000 is less than $50,000 (50 percent of $100,000), the consolidated dividends received deduction is $25,000.

(2) *Example 2.* Assume the same facts as in paragraph (c)(1) of this section (*Example 1*), except that consolidated taxable income (computed without regard to the consolidated net operating loss deduction and the consolidated dividends received deduction) was $40,000. The aggregate of the dividends received deductions, $42,500, computed without regard to section 246(b), results in a consolidated net operating loss of $2,500. *See* section 172(d)(5). Therefore, paragraph (a)(2) of this section does not apply and the consolidated dividends received deduction is $42,500.

§ 1.1502–27 [Removed]

■ **Par. 22.** Section 1.1502–27 is removed.

■ **Par. 23.** Section 1.1502–32 is amended by:

■ 1. Revising paragraphs (b)(4)(v) and (vii).

■ 2. In paragraph (b)(5)(ii), designating *Examples 1* through *10* as paragraphs (b)(5)(ii)(A) through (J), respectively.

■ 3. In newly redesignated paragraphs (b)(5)(ii)(A) through (J), further redesignating paragraphs in the first column as paragraphs in the second column:

Old paragraphs	New paragraphs
(b)(5)(ii)(A)(a), (b), and (c)	(b)(5)(ii)(A)(*1*), (*2*), and (*3*).
(b)(5)(ii)(B)(a), (b), (c), and (d)	(b)(5)(ii)(B)(*1*), (*2*), (*3*), and (*4*).
(b)(5)(ii)(C)(a) and (b)	(b)(5)(ii)(C)(*1*) and (*2*).
(b)(5)(ii)(D)(a), (b), (c), and (d)	(b)(5)(ii)(D)(*1*), (*2*), (*3*), and (*4*).
(b)(5)(ii)(E)(a), (b), and (c)	(b)(5)(ii)(E)(*1*), (*2*), and (*3*).
(b)(5)(ii)(F)(i) and (ii)	(b)(5)(ii)(F)(*1*) and (2).
(b)(5)(ii)(H)(a), (b), and (c)	(b)(5)(ii)(H)(*1*), (*2*), and (*3*).
(b)(5)(ii)(I)(a), (b), and (c)	(b)(5)(ii)(I)(*1*), (*2*), and (*3*).
(b)(5)(ii)(J)(a), (b), and (c)	(b)(5)(ii)(J)(*1*), (*2*), and (*3*).

■ 4. Removing the text ''is treated as a dividend under section 356(a)(2)'' from the last sentence of newly designated paragraph (b)(5)(ii)(F)(*1*) and adding the text ''is treated as received by M in a separate transaction occurring immediately after the merger of T into S'' in its place.

■ 5. In paragraph (b)(5), for each newly redesignated paragraph listed in the ''Paragraph'' column, removing the text indicated in the ''Remove'' column and adding in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(b)(5)(ii)(A)*(2)*	paragraph (a) of this *Example 1*	paragraph (b)(5)(ii)(A)(*1*) of this section (*Example 1*).
(b)(5)(ii)(A)*(3)*	paragraph (b) of this *Example 1*	paragraph (b)(5)(ii)(A)(*2*) of this section (*Example 1*).
(b)(5)(ii)(B)*(2)*	paragraph (a) of this *Example 2*	paragraph (b)(5)(ii)(B)(*1*) of this section (*Example 2*).
(b)(5)(ii)(B)*(3)*	paragraph (a) of this *Example 2*	paragraph (b)(5)(ii)(B)(*1*) of this section (*Example 2*).
(b)(5)(ii)(B)*(4)*	paragraph (a) of this *Example 2*	paragraph (b)(5)(ii)(B)(*1*) of this section (*Example 2*).
(b)(5)(ii)(D)*(3)*	paragraph (a) of this *Example 4*	paragraph (b)(5)(ii)(D)(*1*) of this section (*Example 4*).
(b)(5)(ii)(E)*(2)*	paragraph (a) of this *Example 5*	paragraph (b)(5)(ii)(E)(*1*) of this section (*Example 5*).
(b)(5)(ii)(E)*(3)*	paragraph (a) of this *Example 5*	paragraph (b)(5)(ii)(E)(*1*) of this section (*Example 5*).
(b)(5)(ii)(H)*(2)*	paragraph (a) of this *Example 8*	paragraph (b)(5)(ii)(H)(*1*) of this section (*Example 8*
(b)(5)(ii)(I)*(3)*	paragraph (a) of this *Example 9*	paragraph (b)(5)(ii)(I)(*1*) of this section (*Example 9*).

■ 6. Removing the last sentence of paragraph (h)(2)(i).

■ 7. Removing paragraph (h)(5)(i).

■ 8. Redesignating paragraph (h)(5)(ii) as paragraph (h)(5).

■ 9. Removing the last sentence of paragraphs (h)(6), (h)(7), and (h)(8).

■ 10. Removing the text ''(b)(5)(ii) *Example 6* of this section'' from paragraph (h)(8) and adding the text ''(b)(5)(ii)(F) of this section (*Example 6*)'' in its place.

■ 11. Redesignating paragraph (j) as paragraph (h)(10).

■ 12. Revising the heading of newly designated paragraph (h)(10).

■ 13. Removing the last sentence of newly designated paragraph (h)(10).

■ 14. Removing paragraph (k).

The revisions read as follows:

§ 1.1502–32 Investment adjustments.

* * * * *

(b) * * *

(4) * * *

(v) *Special rule for loss carryovers of a subsidiary acquired in a transaction for which an election under § 1.1502–20(i)(2) is made.* See paragraph (b)(4)(v) of this section as contained in 26 CFR part 1 revised as of April 1, 2005.

* * * * *

(vii) *Special rules for amending waiver of loss carryovers from separate return limitation year relating to the acquisition of a subsidiary in a transaction subject to § 1.1502–20.* See paragraph (b)(4)(vii) of this section as contained in 26 CFR part 1 revised as of April 1, 2005.

* * * * *

(h) * * *

(10) *Election to treat loss carryover as expiring.* * * *

* * * * *

■ **Par. 24.** Section 1.1502–34 is revised to read as follows:

§ 1.1502–34 Special aggregate stock ownership rules.

(a) Determination of stock ownership—(1) *Aggregation rule.* For purposes of the consolidated return regulations, in determining the stock ownership of a member of a group in another corporation (issuing corporation) for purposes of determining the application of section 165(g)(3)(A), section 332(b)(1), section 351(a), section 732(f), or section 904(f) in a consolidated return year, stock in the issuing corporation owned by all other members of the group is included. For the determination of whether a member of the group is an 80-percent distributee, *see* section 337(c) (providing that, for purposes of section 337, the determination of whether any corporation is an 80-percent distributee is made without regard to any consolidated return regulation).

(2) *Example regarding liquidation of member.* The following example illustrates the stock ownership aggregation rule set forth in paragraph (a)(1) of this section.

(i) *Facts.* P wholly owns A, B, and C, each of which is a member of the P group. A, B, and C each owns 33⅓ percent of the stock of D. D liquidates in a transaction purported to qualify under section 332.

(ii) *Analysis.* For purposes of determining satisfaction of the 80-percent stock ownership requirement under section 332(b)(1), under the stock ownership aggregation rule set forth in paragraph (a)(1) of this section: A is treated as owning all of the D stock owned by B and C; B is treated as owning all of the D stock owned by A and C; and C is treated as owning all of the D stock owned by A and B. Therefore, each of A, B, and C is treated as owning 100 percent of the stock of D and thus meeting the 80-percent stock ownership requirement for purposes of section 332. However, none of A, B, or C is treated as an 80-percent distributee for purposes of section 337. *See* section 337(c). Therefore, section 337(a) does not apply.

(b) [Reserved]

§ 1.1502–42 [Removed]

■ **Par. 25.** Section 1.1502–42 is removed.

■ **Par. 26.** Section 1.1502–43 is amended by:

■ 1. Revising paragraphs (b)(2)(iii) through (vi), the last sentence of

paragraph (b)(2)(vii), and paragraph (b)(2)(viii).

■ 2. Removing the last two sentences of paragraph (e).

The revisions read as follows:

§ 1.1502–43 Consolidated accumulated earnings tax.

* * * * *

(b) * * *

(2) * * *

(iii) Under section 535(b)(3), the deduction determined under § 1.1502–26 is not allowed.

(iv) Under section 535(b)(4), the consolidated net operating loss deduction described in § 1.1502–21(a) is not allowed.

(v) Under section 535(b)(5), there is allowed as a deduction the consolidated net capital loss, determined under § 1.1502–22(a).

(vi) Under section 535(b)(6), there is allowed as a deduction an amount equal to—

(A) The consolidated capital gain net income for the taxable year (determined under § 1.1502–22(a) and without the consolidated net capital loss carryovers and carrybacks to the taxable year), minus

(B) The taxes attributable to such gain.

(vii) * * * See § 1.1502–22(b).

(viii) Section 1.1502–15 does not apply.

* * * * *

■ **Par. 27.** Section 1.1502–44 is amended by:

■ 1. Removing the text ''.'' from the end of paragraph (b)(1) and adding the text ''; '' in its place.

■ 2. Revising paragraphs (b)(2) and (3).

The revisions read as follows:

§ 1.1502–44 Percentage depletion for independent producers and royalty owners.

* * * * *

(b) * * *

(2) Any consolidated net operating loss carryback to the consolidated return year under § 1.1502–21; and

(3) Any consolidated net capital loss carryback to the consolidated return year under § 1.1502–22.

* * * * *

■ **Par. 28.** Section 1.1502–45 is added to read as follows:

§ 1.1502–45 Limitation on losses to amount at risk.

(a) *In general*—(1) *Scope.* This section applies to a loss of any subsidiary if the common parent's stock meets the stock ownership requirement described in section 465(a)(1)(B.

(2) *Limitation on use of losses.* Except as provided in paragraph (a)(4) of this section, a loss from an activity of a subsidiary during a consolidated return year is includible in the computation of consolidated taxable income (or consolidated net operating loss) and consolidated capital gain net income (or consolidated net capital loss) only to the extent the loss does not exceed the amount that the parent is at risk in the activity at the close of that subsidiary's taxable year. In addition, the sum of a subsidiary's losses from all its activities is includible only to the extent that the parent is at risk in the subsidiary at the close of that year. Any excess may not be taken into account for the consolidated return year but will be treated as a deduction allocable to that activity of the subsidiary in the first succeeding taxable year.

(3) *Amount parent is at risk in subsidiary's activity.* The amount the parent is at risk in an activity of a subsidiary is the lesser of the amount the parent is at risk in the subsidiary, or the amount the subsidiary is at risk in the activity. These amounts are determined under paragraph (b) of this section and the principles of section 465. *See* section 465 and the regulations thereunder and the examples in paragraph (e) of this section.

(4) *Excluded activities.* The limitation on the use of losses in paragraph (a)(2) of this section does not apply to a loss attributable to an activity described in section 465(c)(4).

(5) *Substance over form.* Any transaction or arrangement between members (or between a member and a person that is not a member) which does not cause the parent to be economically at risk in an activity of a subsidiary will be treated in accordance with the substance of the transaction or arrangement notwithstanding any other provision of this section.

(b) *Rules for determining amount at risk*—(1) *Excluded amounts.* The amount a parent is at risk in an activity of a subsidiary at the close of the subsidiary's taxable year does not include any amount that would not be taken into account under section 465 were the subsidiary not a separate corporation. Thus, for example, if the amount a parent is at risk in the activity of a subsidiary is attributable to nonrecourse financing, the amount at risk is not more than the fair market value of the property (other than the subsidiary's stock or debt or assets) pledged as security.

(2) *Guarantees.* If a parent guarantees a loan by a person other than a member to a subsidiary, the loan increases the amount the parent is at risk in the activity of the subsidiary.

(c) *Application of section 465.* This section applies in a manner consistent with the provisions of section 465. Thus, for example, the recapture of losses provided in section 465(e) applies if the amount the parent is at risk in the activity of a subsidiary is reduced below zero.

(d) *Other consolidated return provisions unaffected.* This section limits only the extent to which losses of a subsidiary may be used in a consolidated return year. This section does not apply for other purposes, such as §§ 1.1502–32 and 1.1502–19, relating to investment in stock of a subsidiary and excess loss accounts, respectively. Thus, a loss which reduces a subsidiary's earnings and profits in a consolidated return year, but is disallowed as a deduction for the year by reason of this section, may nonetheless result in a negative adjustment to the basis of an owning member's stock in the subsidiary or create (or increase) an excess loss account.

(e) *Examples.* The provisions of this section may be illustrated by the examples in this paragraph (e). In each example, the stock ownership requirement of section 465(a)(1)(B) is met for the stock of the parent (P), and each affiliated group files a consolidated return on a calendar year basis and comprises only the members described.

(1) *Example 1.* In 2022, P forms S with a contribution of $200 in exchange for all of S's stock. During the year, S borrows $400 from a commercial lender and P guarantees $100 of the loan. S uses $500 of its funds to acquire a motion picture film. S incurs a loss of $120 for the year with respect to the film. At the close of 2022, the amount P is at risk in S's activity is $300 ($200 contribution plus $100 guarantee). If S has no gain or loss in 2023, and there are no contributions from or distributions to P, at the close of 2023 P's amount at risk in S's activity will be $180.

(2) *Example 2.* P forms S–1 with a capital contribution of $1 on January 1, 2023. On February 1, 2023. S–1 borrows $100 with full recourse and contributes all $101 to its newly formed subsidiary S–2. S–2 uses the proceeds to explore for natural oil and gas resources. S–2 incurs neither gain nor loss from its explorations during the taxable year. As of December 31, 2023, P is at risk in the exploration activity of S–2 only to the extent of $1.

(f) *Applicability date.* This section applies to consolidated return years ending on or after [the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 29.** Section 1.1502–47 is amended by:

■ 1. Italicizing the text ''Nonlife insurance company'' in the heading of paragraph (b)(2).
■ 2. Italicizing the text ''separate return limitation year'' wherever it appears in paragraph (b)(11).
■ 3. Adding the text '','' after the text ''base period'' in paragraph (b)(12)(i).
■ 4. Removing the extra space between the text ''paragraphs (b)(12)'' and the text ''(iii) through (vi)'' in paragraph (b)(12)(i)(A).
■ 5. Removing the extra space between the text ''paragraphs (b)(12)'' and the text ''(v) and (vi)'' in the first sentence of paragraphs (b)(12)(iii) and (iv).
■ 6. Removing the text ''subdivision (iv)'' from the last sentence of paragraph (b)(12)(iv) and adding the text ''paragraph (b)(12)(iv)'' in its place.
■ 7. Removing the extra space between the text ''1.1502–75'' and the text ''(d)(2) or (d)(3)'' in paragraph (b)(12)(vi).
■ 8. Removing the extra space between the text ''paragraph (b)(12)'' and the text ''(ii) through (iv)'' in paragraph (b)(12)(vi).
■ 9. Adding a period after the heading in paragraph (b)(14).
■ 10. Removing the text ''subparagraph (b)(12)(v)(B) and (E)'' from paragraph (b)(14)(iii) and adding the text ''paragraphs (b)(12)(v)(B) and (D)'' in its place.
■ 11. Removing the extra space between the text ''351'' and the text ''(a)'' in paragraph (b)(14)(iii).
■ 12. Removing the text ''the result'' from paragraph (b)(14)(vi) and adding the text ''The result'' in its place.
■ 13. Revising paragraph (c)(2)(ii).
■ 14. Removing the text ''subdivision (ix) of this paragraph (h)(3)'' from paragraph (h)(3)(i) and adding the text ''paragraph (h)(3)(ix) of this section'' in its place.
■ 15. Removing the text ''paragraph (g)(4)'' from paragraph (h)(3)(ii) and adding the text ''paragraph (g)(3)'' in its place.
■ 16. Designating the first and second sentences of the undesignated paragraph after paragraph (h)(3)(x) as paragraphs (h)(3)(x)(A) and (B), respectively.
■ 17. Removing the text ''(as defined in paragraph (j) of this section)'' from newly designated paragraph (h)(3)(x)(B).
■ 18. Removing the text ''paragraph (f)'' from paragraph (h)(4) and adding the text ''paragraph (h)'' in its place.
■ 19. Removing the text ''paragraph (f)(4)(i)'' from the first sentence of paragraph (h)(4)(ii)(A) and adding the text ''paragraph (h)(4)(i)'' in its place.
■ 20. Removing the text ''paragraph (f)(3)(vi)'' from the third sentence of paragraph (h)(4)(ii)(A) and adding the text ''paragraph (h)(3)(vi)'' in its place.
■ 21. Removing the text ''paragraph (f)(3)(x)'' from the fifth sentence of paragraph (h)(4)(ii)(A) and adding the text ''paragraph (h)(3)(x)'' in its place.
■ 22. Removing the text ''paragraph (f)(2)(ii)'' from the seventh sentence of paragraph (h)(4)(ii)(A) and adding the text ''paragraph (h)(2)(ii)'' in its place.
■ 23. Removing the text ''paragraph (f)(4)(ii)'' from the first sentence of paragraph (h)(4)(iii) and adding the text ''paragraph (h)(4)(ii)'' in its place.
■ 24. Removing the text ''paragraph (f)(3)(vi)'' from the fourth sentence of paragraph (h)(4)(iii) and adding the text ''paragraph (h)(3)(vi)'' in its place.
■ 25. Removing the text ''paragraph (f)(3)(ii)'' from the fifth sentence of paragraph (h)(4)(iii) and adding the text ''paragraph (h)(3)(ii)'' in its place.
■ 26. Italicizing the text ''In'' in the heading of paragraph (j)(1).
■ 27. In paragraph (m)(1)(i), removing the text ''or'', and adding the text ''or any successor form'' at the end of the paragraph.
■ 28. Adding the text ''or any successor form,'' before the text ''whether filed'' in paragraphs (m)(1)(iv) and (m)(1)(v).

The revision reads as follows:

§ 1.1502–47 Consolidated returns by life-nonlife groups.

* * * * *

(c) * * *

(2) * * *

(ii) *Special rule.* Notwithstanding the general rule, however, if the nonlife members in the group filed a consolidated return for the immediately preceding taxable year and had executed and filed a Form 1122 (or successor form) that is effective for the preceding year, then such members will be treated as if they filed a Form 1122 (or successor form) when they join in the filing of a consolidated return under section 1504(c)(2) and they will be deemed to consent to the regulations under this section. However, an affiliation schedule (Form 851, or any successor form) must be filed by the group and the life members must execute a Form 1122 (or successor form) in the manner prescribed in § 1.1502–75(h)(2).

* * * * *

■ **Par. 30.** Section 1.1502–75 is amended by:
■ 1. Adding the text ''(or successor form)'' after the text ''Form 1122'' wherever it appears in paragraph (b)(1).
■ 2. Adding the text ''(or successor form'') after the text ''Form 851'' in paragraph (b)(2)(iii).
■ 3. Adding the text ''(or successor form)'' after the text ''Form 1122'' wherever it appears in paragraph (b)(3)
■ 4. Revising the second sentence of paragraph (c)(1)(i).
■ 5. Removing the text ''his'' from paragraphs (c)(2)(i) and (ii) and adding the text ''the Commissioner's'' in its place.
■ 6. Removing paragraph (d)(5).
■ 7. Revising paragraph (h)(1).
■ 8. Adding the text '', or any successor form,'' before the text ''must be executed'' in the first sentence of paragraph (h)(2), removing the second sentence and revising the third sentence.
■ 9. Adding the text ''(or successor forms)'' after the text ''Forms 1122'' in the fourth sentence of paragraph (h)(2).
■ 10. Adding the text ''(or any successor form)'' after the text ''Form 1122'' in the last sentence of paragraph (h)(2).

The revisions read as follows:

§ 1.1502–75 Filing of consolidated returns.

* * * * *

(c) * * *

(1) * * *

(i) * * * Any such application must be made through a letter ruling request filed not later than the 90th day before the due date of the consolidated return for the taxable year (including extensions). * * *

* * * * *

(h) *Method of filing returns and forms*—(1) *Consolidated return made by common parent or agent.* The consolidated return must be made on Form 1120, *U.S. Corporation Income Tax Return* (or any successor form), for the group by the common parent or the agent for the group as provided in § 1.1502–77(c). The consolidated return, with Form 851, *Affiliations Schedule* (or any successor form), attached, must be filed with the service center with which the common parent would have filed a separate return.

(2) * * * The group must attach either executed Forms 1122 (or successor forms) or unsigned copies of the completed Forms 1122 (or successor forms) to the consolidated return. * * *

* * * * *

■ **Par. 31.** Section 1.1502–76 is amended by:
■ 1. Revising the last sentence of paragraph (a).
■ 2. Removing the last sentence from paragraphs (b)(1)(ii)(A)*(2)* and (b)(2)(v).
■ 3. Revising paragraph (b)(6).
■ 4. Designating *Example 1* and *2* in paragraph (c)(3) as paragraphs (c)(3)(i) and (ii), respectively.
■ 5. In newly designated paragraph (c)(3)(i), removing the text ''June 15'' wherever it appears and adding the text ''July 15'' in its place, and removing the text ''March 15'' wherever it appears and adding the text ''April 15'' in its place.
■ 6. In newly redesignated paragraph (c)(3)(i), removing the text ''1966''

wherever it appears and adding the text ''2022'' in its place.

■ 7. In newly redesignated paragraphs (c)(3)(i), removing the text ''1967'' wherever it appears and adding the text ''2023'' in its place.

■ 8. In newly redesignated paragraphs (c)(3)(i), removing the text ''1968'' wherever it appears and adding the text ''2024'' in its place.

■ 9. In newly redesignated paragraph (c)(3)(ii), removing the text ''June 15'' wherever it appears and adding the text ''July 15'' in its place, and removing the text ''March 15'' wherever it appears and adding the text ''April 15'' in its place.

■ 10. In newly redesignated paragraph (c)(3)(ii), removing the text ''1967'' wherever it appears and adding the text ''2023'' in its place.

■ 11. In newly redesignated paragraph (c)(3)(ii), removing the text ''1968'' wherever it appears and adding the text ''2024'' in its place.

■ 12. Revising paragraph (d).

The revisions read as follows:

§ 1.1502–76 Taxable year of members of group.

(a) * * * Any request for such consent must be requested at the time and in the manner that the Commissioner of Internal Revenue may prescribe by Internal Revenue Service forms and instructions or by publication in the Internal Revenue Bulletin (see § 601.601(d)(2)(ii) of this chapter).

(b) * * *

(6) *Applicability date.* Except as provided in paragraphs (b)(1)(ii)(A)(*2*) and (b)(2)(v) of this section, this paragraph (b) applies to corporations becoming or ceasing to be members of consolidated groups on or after January 1, 1995.

* * * * *

(d) *Applicability date*—(1) *Taxable years of members of group applicability date.* Paragraph (a) of this section applies to any original consolidated Federal income tax return due (without extensions) after July 20, 2007.

(2) *Election to ratably allocate items applicability date.* Paragraph (b)(2)(ii)(D) of this section applies to any original consolidated Federal income tax return due (without extensions) after July 20, 2007.

§ 1.1502–77 [Amended]

■ **Par. 32.** Section 1.1502–77 is amended by:

■ 1. Designating *Examples 1* through *15* in paragraph (g) as paragraphs (g)(1) through (15), respectively.

■ 2. In paragraph (g), for each newly redesignated paragraph listed in the ''Paragraph'' column, removing the text indicated in the ''Remove'' column and adding in its place the text indicated in the ''Add'' column:

Paragraph	Remove	Add
(g)(2)(i)	Example 1	paragraph (g)(1)(i) of this section (*Example 1*).
(g)(4)(i)	*Example 3*	paragraph (g)(3)(i) of this section (*Example 3*).
(g)(5)(i)	*Example 4*	paragraph (g)(4) of this section (*Example 4*).
(g)(11)(i)(B)(*1*)	his	the Commissioner's.
(g)(11)(ii)(A)	paragraph (i)(A) of this *Example 11*	paragraph (g)(11)(i)(A) of this section.
(g)(12)(i)	paragraph (ii)(A) of *Example 11*	paragraph (g)(11)(ii)(A) of this section (*Example 11*).
(g)(13)(i)	March 15	April 15.

§ 1.1502–77A [Amended]

■ **Par. 33.** Section 1.1502–77A is amended by removing the text ''he may, if he deems it advisable,'' from the last sentence of paragraph (d) and adding the text ''the Commissioner may'' in its place.

§ 1.1502–77B [Amended]

■ **Par. 34.** Section 1.1502–77B is amended by:

■ 1. Removing the text ''he may, if he deems it advisable,'' from the last sentence of paragraph (a)(6)(i) and adding the text ''the Commissioner may'' in its place.

■ 2. Removing the text ''he'' from paragraph (a)(6)(ii) and adding the text ''the Commissioner'' in its place.

■ **Par. 35.** Section 1.1502–78 is amended by revising paragraph (f) to read as follows:

§ 1.1502–78 Tentative carryback adjustments.

* * * * *

(f) *Applicability date.* This section applies to taxable years to which a loss or credit may be carried back and for which the due date (without extensions) of the original return is after June 28, 2002, except that the provisions of paragraph (e)(2) of this section apply for applications by new members of consolidated groups for tentative carryback adjustments resulting from net operating losses, net capital losses, or unused business credits arising in separate return years of new members that begin on or after January 1, 2001.

■ **Par. 36.** Section 1.1502–79 is amended by:

■ 1. Revising paragraphs (a), (b), and (d).

■ 2. Removing the text ''(or §§ 1.1502–79A(a)(1) and (2), as appropriate)'' from paragraph (e)(1).

■ 3. Revising paragraph (e)(2).

The revisions read as follows:

§ 1.1502–79 Separate return years.

(a) *Carryover and carryback of consolidated net operating losses to separate return years.* For rules regarding the carryover and carryback of consolidated net operating losses to separate return years, see § 1.1502–21(b).

(b) *Carryover and carryback of consolidated net capital loss to separate return years.* For rules regarding the carryover and carryback of consolidated net capital losses to separate return years, see § 1.1502–22(b).

* * * * *

(d) *Carryover and carryback of consolidated unused foreign tax*—(1) *In general.* If a consolidated unused foreign tax can be carried under the principles of section 904(c) and § 1.1502–4(d) to a separate return year of a corporation (or could have been so carried if such corporation were in existence) that was a member of the group in the year in which the unused foreign tax arose, then the portion of the consolidated unused foreign tax attributable to the corporation (as determined under paragraph (d)(2) of this section) is apportioned to the corporation (and any successor to that corporation in a transaction to which section 381(a) applies) under the principles of § 1.1502–21(b) and is deemed paid or accrued in such separate return year to the extent provided in section 904(c).

(2) *Portion of consolidated unused foreign tax attributable to a member.* The portion of a consolidated unused foreign tax for any year attributable to a member is an amount equal to the consolidated unused foreign tax multiplied by a fraction. The numerator of the fraction is the foreign taxes paid or accrued by the member for the year (including those taxes deemed paid or accrued, other than by reason of section 904(c)). The denominator of the fraction

is the aggregate of all such taxes paid or accrued for the year (including those taxes deemed paid or accrued, other than by reason of section 904(c)) by all members of the group.

(e) * * *

(2) *Portion of consolidated excess charitable contributions attributable to a member.* The portion of the consolidated excess charitable contributions for any year attributable to a member is an amount equal to the consolidated excess contributions multiplied by a fraction. The numerator of the fraction is the charitable contributions paid by the member for the year. The denominator of the fraction is the aggregate of all charitable contributions paid for the year by all members of the group.

* * * * *

§ 1.1502–80 [Amended]

■ **Par. 37.** Section 1.1502–80 is amended by removing the text ''on or after September 17, 2008'' from paragraph (c)(2).

§ 1.1502–81T [Removed]

■ **Par. 38.** Section 1.1502–81T is removed.

■ **Par. 39.** Section 1.1502–90 is amended by revising the entry in the table of contents for § 1.1502–99, in numerical order, to read as follows:

§ 1.1502–90 Table of contents.

* * * * *

§ 1.1502–99 Effective/applicability dates.

(a) In general.

(b) Reattribution of losses under § 1.1502–36(d)(6).

(c) Application to section 163(j).

(1) Sections 1.382–2 and 1.382–5.

(2) Sections 1.382–6 and 1.383–1.

§ 1.1502–91 [Amended]

■ **Par. 40.** Section 1.1502–91 is amended by removing paragraph (b)(3).

§ 1.1502–92 [Amended]

■ **Par. 41.** Section 1.1502–92 is amended by:

■ 1. Designating *Examples 1* through *3* in paragraph (b)(3)(iii) as paragraphs (b)(3)(iii)(A) through (C), respectively.

■ 2. In newly redesignated paragraphs (b)(3)(iii)(A) through (C), further redesignating paragraphs in the first column as paragraphs in the second column:

Old paragraphs	New paragraphs
(b)(3)(iii)(A)(i) and (ii)	(b)(3)(iii)(A)(*1*) and (*2*).
(b)(3)(iii)(B)(i), (ii), (iii), and (iv)	(b)(3)(iii)(B)(*1*), (*2*), (*3*), and (*4*).
(b)(3)(iii)(C)(i) and (ii)	(b)(3)(iii)(C)(*1*) and (*2*).

■ 3. Removing the text ''his'' from newly redesignated paragraph (b)(3)(iii)(B)(*2*) and adding the text ''its'' in its place.

■ **Par. 42.** Section 1.1502–99 is amended by:

■ 1. Revising paragraphs (a) and (b).

■ 2. Removing paragraph (c).

■ 3. Redesignating paragraph (d) as paragraph (c).

The revisions read as follows:

§ 1.1502–99 Effective/applicability dates.

(a) *In general.* Sections 1.1502–91 through 1.1502–96 and § 1.1502–98 apply to any testing date that is on or after June 25, 1999. Sections 1.1502–94 through 1.1502–96 also apply to a corporation that becomes a member of a group or ceases to be a member of a group (or loss subgroup) on or after June 25, 1999.

(b) *Reattribution of losses under § 1.1502–36(d)(6).* Section 1.1502–96(d) applies to reattributions of net operating loss carryovers, capital loss carryovers, and deferred deductions in connection with a transfer of stock to which § 1.1502–36 applies, and the election under § 1.1502–96(d)(5) (relating to an election to reattribute section 382 limitation) can be made with an election under § 1.1502–36(d)(6) to reattribute a loss to the common parent that is filed at the time and in the manner provided in § 1.1502–36(e)(5)(x).

* * * * *

■ **Par. 43.** Section 1.1502–100 is amended by:

■ 1. Removing the text ''§ 1.1502–1 through § 1.1502–80'' from paragraph (a)(2) wherever it appears and adding the text ''the consolidated return regulations'' in its place.

■ 2. Removing the text ''1.1502–21A or'' and the text ''(as appropriate)'' from paragraph (c)(2).

■ 3. Revising paragraph (d).

The revision reads as follows:

§ 1.1502–100 Corporations exempt from tax.

* * * * *

(d) *Separate unrelated business taxable income*—(1) *In general.* The separate unrelated business taxable income of a member of an exempt group must be computed in accordance with the provisions of section 512 covering the determination of unrelated business taxable income of separate corporations, except that:

(i) The provisions of paragraphs (a) through (d), (f) through (k), and (o) of § 1.1502–12 apply; and

(ii) No charitable contributions deduction is taken into account under section 512(b)(10).

(2) *Section 501(c)(2) organizations.* See sections 511(c) and 512(a)(3)(C) for special rules applicable to organizations described in section 501(c)(2).

§§ 1.1502–9A, 1.1502–15A, 1.1502–21A, 1.1502–22A, 1.1502–23A, 1.1502–41A, 1.1502–79A, 1.1502–90A, 1.1502–91A, 1.1502–92A, 1.1502–93A, 1.1502–94A, 1.1502–95A, 1.1502–96A, 1.1502–97A, 1.1502–98A, 1.1502–99A, and 1.1503–2 [Removed]

■ **Par. 44.** Sections 1.1502–9A, 1.1502–15A, 1.1502–21A, 1.1502–22A, 1.1502–23A, 1.1502–41A, 1.1502–79A, 1.1502–90A, 1.1502–91A, 1.1502–92A, 1.1502–93A, 1.1502–94A, 1.1502–95A, 1.1502–96A, 1.1502–97A, 1.1502–98A, 1.1502–99A, and 1.1503–2 are removed.

§ 1.1503–2 [Removed]

■ **Par. 45.** Section 1.1503–2 is removed.

§ 1.1503(d)–1 [Amended]

■ **Par. 46.** Section 1.1503(d)–1 is amended by removing the text ''possession of the United States'' from paragraph (b)(7) and adding the text ''U.S. territory (as defined in § 1.1502–1(l))'' in its place.

■ **Par. 47.** Section 1.1503(d)–8 is amended by:

■ 1. Revising the last sentence of paragraph (a).

■ 2. Removing and reserving paragraphs (b)(1), (b)(2), (b)(3)(ii), (b)(3)(iii), and (b)(4).

The revision reads as follows:

§ 1.1503(d)–8 Effective dates.

(a) * * * Section 1.1503–2, as contained in 26 CFR part 1, revised as of April 1, 2023, applies for dual consolidated losses incurred in taxable

years beginning on or after October 1, 1992, and before the application date.

* * * * *

■ **Par. 48.** Section 1.1552–1 is amended by:

■ 1. Redesignating paragraphs (a)(1)(ii)*(a)* through *(d)* as paragraphs (a)(1)(ii)(A) through (D), respectively.

■ 2. Revising newly redesignated paragraph (a)(1)(ii)(B).

■ 3. Redesignating paragraphs (a)(2)(ii)*(a)* through *(i)* as paragraphs (a)(2)(ii)(A) through (I), respectively.

■ 4. Removing and reserving newly redesignated paragraph (a)(2)(ii)(B).

■ 5. Revising paragraph (a)(2)(ii)(I).

The revisions read as follows:

§ 1.1552–1 Earnings and Profits.

(a) * * *

(1) * * *

(ii) * * *

(B) Such member's capital gain net income (determined without regard to any net capital loss carryover attributable to such member);

* * * * *

(2) * * *

(ii) * * *

(I) For purposes of subtitle A of the Code, if two or more taxable income brackets are set forth in section 11(b) of the Code, the amount in each taxable income bracket is divided by the number of members (or such portion of each bracket which is apportioned to the member pursuant to a schedule attached to the consolidated return for the consolidated return year). However, if for the taxable year some or all of the members are component members of a controlled group of corporations (within the meaning of section 1563) and if there are other such component members which do not join in filing the consolidated return for such year, the amount to be divided among the members filing the consolidated return is (in lieu of the taxable income brackets) the sum of the amounts apportioned to the component members which join in filing the consolidated return.

* * * * *

§ 1.1563–1 [Amended]

■ **Par. 49.** Section 1.1563–1 is amended by:

■ 1. Removing the text ''(directly and with the application of § 1.1563–3(b)(1), relating to options)'' from paragraph (a)(2) wherever it appears and adding the text ''(directly and with the application of § 1.1563–3(b)(1), (2), and (3))'' in its place.

■ 2. Removing the text ''his'' from paragraph (a)(6) wherever it appears and adding the text ''the shareholder's'' in its place.

■ 3. In paragraph (b)(4), designating *Examples 1* through *4* as paragraphs (b)(4)(i) through (iv), respectively.

■ 4. Removing the text ''he'' from the third sentence of newly designated paragraph (b)(4)(i) and adding the text ''B'' in its place.

§ 1.1563–2 [Amended]

■ **Par. 50.** Section 1.1563–2 is amended by:

■ 1. Removing the text ''his'' from each of paragraphs (b)(2)(iii) and (b)(4)(ii), and adding the text ''the employee's'' in its place.

■ 2. In paragraph (b)(7), designating *Examples 1* through *3* as paragraphs (b)(7)(i) through (iii), respectively.

■ 3. In newly designated paragraph (b)(7)(iii), removing the text ''he'' wherever it appears and adding the text ''Davis'' in its place; removing the text ''his'' wherever it appears and adding the text ''Davis's'' in its place; and removing the text ''wife'' from the last sentence and adding the text ''spouse'' in its place.

§ 1.1563–3 [Amended]

■ **Par. 51.** Section 1.1563–3 is amended by:

■ 1. Removing the text ''his'' from paragraph (b)(2)(i) and adding the text ''the partner's'' in its place.

■ 2. Removing the text ''The provisions of this subparagraph may be illustrated by the following example:'' from paragraph (b)(2)(ii).

■ 3. Removing the text ''his'' from the fourth sentence of paragraph (b)(2)(ii) and adding the text ''Green's'' in its place.

■ 4. In the sixth sentence of paragraph (b)(2)(ii), removing the text ''he'' and adding the text ''Jones'' in its place, and removing the text ''his'' and adding the text ''Jones's'' in its place.

■ 5. Removing the text ''he'' from the last sentence of paragraph (b)(2)(ii) and adding the text ''White'' in its place.

■ 6. In paragraph (b)(3)(i), removing the text ''his'' from the second sentence and adding the text ''the beneficiary's'' in its place, and removing the text ''he'' and ''him'' from the second-to-last sentence and adding the text ''that beneficiary'' in its place.

■ 7. In paragraph (b)(3)(ii), removing the text ''his'' and adding the text ''the decedent's'' in its place, and removing the text ''he'' and ''him'' wherever it appears and adding the text ''the person'' in its place.

■ 8. Removing the text ''The provisions of this subparagraph may be illustrated by the following example:'' from paragraph (b)(4)(ii).

■ 9. In paragraph (b)(4)(ii), removing the text ''he'' from the fifth sentence and adding the text ''Smith'' in its place, and removing the text ''Smith's wife'' and ''his wife'' from the last sentence wherever it appears and adding the text ''Smith's spouse'' in its place.

■ 10. Removing the text ''his'' from paragraphs (b)(5)(i) and (ii) and (b)(6)(i) and (ii) wherever it appears and adding the text ''the individual's'' in its place.

■ 11. Removing the text ''The provisions of this subparagraph may be illustrated by the following example:'' from paragraph (b)(6)(iv).

■ 12. Redesignating paragraphs (b)(6)(iv)(a) through (d) as paragraphs (b)(6)(iv)(A) through (D).

■ 13. In newly redesignated paragraph (b)(6)(iv)(A), removing the text ''F'' and adding the text ''B'' in its place, and removing the text ''His son'' and ''his son'' and adding the text ''B's child'' in its place.

■ 14. In newly redesignated paragraph (b)(6)(iv)(B), removing the text ''F'' wherever it appears and adding the text ''B'' in its place, removing the text ''subdivision (ii) of this subparagraph'' and adding the text ''paragraph (b)(6)(ii) of this section'' in its place, removing the text ''he'' and adding the text ''B'' in its place, and removing the text ''his adult son'' and adding the text ''B's adult child'' in its place.

■ 15. In the first sentence of newly redesignated paragraph (b)(6)(iv)(C), removing the text ''son'' and adding the text ''child'' in its place, and removing the text ''by his father, F'' and adding the text ''by B'' in its place.

■ 16. In the second sentence of newly redesignated paragraph (b)(6)(iv)(C), removing the text ''his brother'' and adding the text ''M's sibling'' in its place, removing the text ''F'' wherever it appears and adding the text ''B'' in its place, removing the text ''him'' and adding the text ''B'' in its place, and removing the text ''his'' and adding the text ''B's'' in its place.

■ 17. In newly redesignated paragraph (b)(6)(iv)(D), removing the text ''son'' and adding the text ''child'' in its place, removing the text ''he'' wherever it appears and adding the text ''A'' in its place, and removing the text ''his father'' and adding the text ''B'' in its place.

■ 18. Removing the text ''him'' from paragraph (c)(2) and adding the text ''the individual'' in its place.

■ 19. In paragraph (c)(4), designating *Examples 1* through *3* as paragraphs (c)(4)(i) through (iii), respectively.

■ 20. In newly designated paragraph (c)(4)(ii), removing the text ''brother'' from the second sentence and adding the text ''sibling'' in its place, and removing the text ''father'' from the

third sentence and adding the text ''parent'' in its place.
■ 21. Removing the text ''his son,'' from the first sentence of newly designated paragraph (c)(4)(iii).
■ 22. In paragraph (d)(3), designating *Examples 1* through *3* as paragraphs (d)(3)(i) through (iii), respectively.
■ 23. In newly designated paragraph (d)(3)(i), removing the text ''he'' from the third sentence and adding the text ''Smith'' in its place, and removing the text ''his stock in corporation Z'' from the fifth sentence and adding the text ''the corporation Z stock'' in its place.
■ 24. In newly designated paragraph (d)(3)(ii), removing the text ''H'' wherever it appears and adding the text ''A'' in its place, and removing the text ''W'' wherever it appears and adding the text ''B'' in its place.
■ 25. Removing the text ''wife'' from the first sentence of newly designated paragraph (d)(3)(ii) and adding the text ''spouse'' in its place.
■ 26. Removing the text ''subparagraph (2)(iii) of this paragraph'' from the fifth sentence of newly designated paragraph (d)(3)(ii) and adding the text ''paragraph (d)(2)(iii) of this section'' in its place.

PART 5—TEMPORARY INCOME TAX REGULATIONS UNDER THE REVENUE ACT OF 1978

■ **Par. 52.** The authority citation for part 5 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 5.1502–45 [Removed]

■ **Par. 53.** Section 5.1502–45 is removed.

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 54.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

§ 301.6402–7 [Amended]

■ **Par. 55.** Section 301.6402–7 is amended by removing the text ''§§ 1.1502–21(b) or 1.1502–21A(b) (as appropriate)'' from paragraph (g)(2)(iii) and adding the text ''§ 1.1502–21(b)'' in its place.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 56.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

■ **Par. 57.** Section 602.101(b) is amended by removing the entries for §§ 1.1502–9A, 1.1502–18, 1.1502–76T, 1.1502–95A, 1.1503–2, and 1.1503–2A from the table.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2023–14098 Filed 8–4–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

[SATS No. MT–037–FOR; Docket ID: OSM–2021–0006; S1D1S SS08011000 SX064A000 222S180110; S2D2S SS08011000 SX064A000 22XS501520]

Montana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period reopening and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are reopening the public comment period due to the receipt of revisions to a proposed amendment to the Montana regulatory program (hereinafter, the Montana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Montana is proposing revisions to the Administrative Rules of Montana pertaining to ownership and control and the applicant violator system. These changes were required by a March 30, 2023 letter from OSMRE to Montana (hereinafter, issue letter) after our review of Montana's original July 28, 2021 proposed amendment submittal. The July 28, 2021 proposed amendment submittal by Montana was the result of an October 2, 2009, letter from OSMRE to Montana (hereinafter, 732 letter), and were necessitated by a Senate bill approved by the 2013 Montana Legislature. This document gives the times and locations that the Montana program and this revised proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the revised amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., Mountain Daylight Time (MDT), September 6, 2023. If requested, we may hold a public hearing or meeting on the amendment on September 1, 2023. We will accept requests to speak at a hearing until 4:00 p.m., MST on August 22, 2023.

ADDRESSES: You may submit comments, identified by SATS No. MT–037–FOR, by any of the following methods:

- *Mail/Hand Delivery:* 100 East B Street, Room 4100, Casper, WY 82601.
- *Fax:* (307) 421–6552.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID: OSM–2021–0006. If you would like to submit comments go to *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Montana program, this amendment, a listing of any scheduled public hearings or meetings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Denver Field Division or the full text of the program amendment is available for you to read at *www.regulations.gov.*

Jeffrey Fleischman, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, Dick Cheney Federal Building, POB 11018, 100 East B Street, Casper, Wyoming 82601, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov*

In addition, you may review a copy of the amendment during regular business hours at the following location:

Dan Walsh, Chief, Coal and Opencut Mining Bureau, Montana Department of Environmental Quality, P.O. Box 200901, Helena, Montana 59620–0901, Telephone: (406) 444–6791, Email: *dwalsh@mt.gov*

FOR FURTHER INFORMATION CONTACT: Howard Strand, Office of Surface Mining Reclamation and Enforcement, One Denver Federal Center, Building 41, Lakewood, CO 80225–0065, Telephone: (303) 236–2931, Email: *hstrand@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Montana Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Statutory and Executive Order Reviews

I. Background on the Montana Program

Subject to OSMRE's oversight Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its approved, State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Montana program on April 1, 1980. You can find background information on the Montana program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Montana program in the April 1, 1980, **Federal Register** (45 FR 21560). You can also find later actions concerning the Montana program and program amendments at 30 CFR 926.15, 926.16, and 926.30.

II. Description of the Proposed Amendment

On October 28, 1994, December 19, 2000, and December 3, 2007, OSMRE promulgated final rules that adopted or revised certain regulatory definitions and provisions pertaining to review of applications, permit eligibility, application information, applicant, operator, and permittee information, automated information entry and maintenance, permit suspension and rescission, ownership and control findings and challenge procedures, transfer, assignment, or sale of permit rights, and alternative enforcement. Pursuant to 30 CFR 732.17(d), OSMRE notified Montana on October 2, 2009 with a 732 letter, requiring Montana to modify its regulatory program to remain consistent with revised Federal requirements. The 2013 Montana Legislature approved Senate Bill 92, which added language addressing the required changes. Specifically, Senate Bill 92 added language in Section 82–4–227, Montana Code Annotated (MCA), that provided appeal rights pertaining to ownership or control listings in the applicant violator system.

By letter dated July 28, 2021 (FDMS Document ID No. OSM–2021–0006–0001), Montana sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) that proposed revisions to existing Administrative Rules of Montana (ARM) that would satisfy the statutory changes in the MCA, including revisions to 17.24.301, 17.24.302, 17.24.303, 17.24.416, 17.24.418. New provisions in the ARM proposed by Montana that would satisfy the statutory changes in the MCA include 17.24.1229, 17.24.1264, 17.24.1265, 17.24.1266, and 17.24.1267. Montana also proposed minor revisions to existing ARM that were unrelated to Senate Bill 92.

OSMRE reviewed the proposed changes to the MCA and ARM, on March 30, 2023, sent Montana an issue letter outlining five areas of concern with their proposed changes to the ARM, including numerous typos and grammatical errors, requiring specific information of the applicant in permit application packages, applying willful or knowing standards for liability regarding characterizing criminal penalties and civil actions, and adding clarifier language to remain as effective and consistent with Federal counterpart rules. By letter dated May 3, 2023, Montana responded and agreed to address all five areas of concern by formally resubmitting the required revisions to the ARM. Montana agreed to making all the necessary typographical and grammatical errors in addition to the other required changes explained above. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov.*

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written or electronic comments on the proposed rule during the 15-day comment period, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., MDT on August 22, 2023. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Statutory and Executive Order Reviews

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory

Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 926

Intergovernmental relations, Surface mining, Underground mining.

David Berry,

Regional Director, Western Region.

[FR Doc. 2023–16847 Filed 8–4–23; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

[SATS No. MT–042–FOR; Docket ID: OSM–2023–0007; S1D1S SS08011000 SX064A000 231S180110; S2D2S SS08011000 SX064A000 23XS501520]

Montana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Montana regulatory program (hereinafter, the Montana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). During the 2023 legislative session, the Montana legislature passed House Bill 576 (HB 576), amending the Montana Strip and Underground Mine Reclamation Act as well as the Montana Code Annotated (MCA). Accordingly, Montana submitted this proposed amendment to OSMRE on its own initiative. Montana's proposal amends the definition of ''Material Damage,'' by changing the requirements for what is considered ''Material Damage'' to the hydrologic balance. Montana's proposal also amends permit requirements for mine operations related to hydrologic information. The amendment removes the requirement that a permit applicant must submit hydrologic information to the Montana Depart of Environmental Quality (DEQ) before DEQ approves the permit application. Lastly, HB 576 adds four contingencies to the proposed amendments of the MCA: a severability clause, a contingent voidness clause, an effective date clause, and a retroactive applicability clause.

This document gives the times and locations that the Montana program and this proposed amendment to the program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., M.D.T, September 6, 2023. If requested, we may hold a public hearing or meeting on the amendment on September 1, 2023. We will accept requests to speak at a hearing until 4:00 p.m., M.D.T. on August 22, 2023.

ADDRESSES: You may submit comments, identified by SATS No. MT–042–FOR, by any of the following methods:

- *Mail/Hand Delivery:* OSMRE, Attn: Jeffrey Fleischman, P.O. Box 11018, 100 East B Street, Room 4100, Casper, Wyoming 82602.
- *Fax:* (307) 261–6552.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID: OSM–2023–0007. If you would like to submit comments, go to *http://www.regulations.gov.* Follow the instructions for submitting comments.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than the ones listed above will be included in the docket for this rulemaking and considered.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Montana program, this amendment, a listing of any scheduled public hearings or meetings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Casper Field Office or the full text of the program amendment is available for you to read at *www.regulations.gov.*

Attn: Jeffrey Fleischman, Field Office Director, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82602, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov*

In addition, you may review a copy of the amendment during regular business hours at the following location:

Attn: Dan Walsh, Mining Bureau Chief, Coal and Opencut Mining Bureau, Department of Environmental Quality, P.O. Box 200901, Helena, MT 59601–0901, Telephone: (406) 444–6791, Email: *dwalsh@mt.gov*

FOR FURTHER INFORMATION CONTACT:

Attn: Jeffrey Fleischman, Field Office Director, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82602, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov*

SUPPLEMENTARY INFORMATION:

I. Background on the Montana Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Montana Program

Subject to OSMRE's oversight Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its approved, State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7).

On the basis of these criteria, the Secretary of the Interior approved the Montana program on October 24, 1980. You can find background information on the Montana program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Montana program in the October

24, 1980, **Federal Register** (45 FR 70445). You can also find later actions concerning the Montana program and program amendments at 30 CFR 926.25.

II. Description of the Proposed Amendment

By letter dated June 1, 2023 (Administrative Record No. MT–042–01), Montana sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). We found Montana's proposed amendment to be administratively complete on June 5, 2023. Montana submitted this proposed amendment to us, of its own volition, following the passage of Montana House Bill 576 (HB 756) during the 2023 legislative session. HB 576 amends the Montana Strip and Underground Mine Reclamation Act as well as § 82–4–203 and § 82–4–222 of MCA. HB 576 also adds four contingencies that apply to the proposed amendments.

First, Montana proposes several changes to § 82–4–203(32), which defines and describes ''Material Damage.'' Currently, this section dictates how ''Material Damage'' applies to the protection of the hydrologic balance. Montana now proposes to create three sub sections under § 82–4–203(32) and will explain how ''Material Damage'' applies to each.

Proposed subsection § 82–4–203(32)(a) would create two requirements for an action or inaction to be considered ''Material Damage'' to the hydrologic balance. The first requirement is that the coal mining operation cause significant, lasting or permanent, adverse changes to water quality or quantity that affect the beneficial uses of, and rights to, the water outside the permit area. This requirement incorporates § 82–4–203(32)'s current language, but with modifications. Montana proposes to replace the phrase ''degradation or reduction'' with ''significant long term or permanent adverse change.'' Montana also removes violations of water quality standards, regardless of whether an existing water use is affected, from the definition of ''Material Damage.'' The second requirement for an action or inaction to be considered ''Material Damage'' to the hydrologic balance is that a coal mining or reclamation operation cause a lasting or permanent exceedance of a water quality standard outside a permit area. There is an exception to this second requirement for water bodies whose water quality standard is stricter than the baseline conditions the DEQ determines when assessing an operation's cumulative hydrologic impacts. For those water bodies, this requirement is instead met if the coal mining and reclamation operation causes an adverse effect to land use, beneficial uses of water, or water rights.

Proposed subsection § 82–4–203(32)(b) would apply when determining if an alluvial valley floor is ''Materially Damaged.'' Montana proposes to modify the definition of ''Material Damage'' by adding language that accounts for the degradation or a reduction of water quality or quantity supplied to an alluvial valley floor by a coal mining and reclamation operation, but only if those actions or inactions significantly decrease the alluvial valley floor's ability to support agricultural activities.

Proposed subsection § 82–4–203(32)(c) would apply when determining if subsidence caused by underground coal mines is ''Material Damage.'' Subsidence caused by underground coal mines would constitute ''Material Damage,'' when there are significant impairments to surface lands, features, and structures; physical changes that have significant adverse effects on a lands current and reasonably foreseeable uses, production, or income; or when there is any significant change to a structure's pre-subsidence condition, appearance, or utility.

Next, Montana proposes to amend its coal mine operation permit requirements related to hydrologic information by removing two sentences from § 82–4–222(1)(m). The first sentence states that the DEQ is not required to determine the probable hydrologic consequences of a coal mining and reclamation operation until the coal mining permit applicant submits the necessary hydrologic information to DEQ. The second sentence prohibits the DEQ from approving a coal mining permit application until the coal mining operation provides necessary hydrologic information to the DEQ.

Lastly, HB 576 adds four contingencies to the proposed amendments of § 82–4–203(32) and § 82–4–222(1)(m) that are not codified into the MCA but apply to the amended sections. Section 4 of HB 576 states that if any or all parts of HB 576 is found invalid, any parts found valid will remain in effect. Section 5 of HB 576 states that if the Secretary of the Interior disapproves any provision of the HB 576, then that portion is void. Section 6 of HB 576 states that HB 576 is effective upon passage and approval. Lastly, Section 7 of HB 576 states that HB 576 applies retroactively to actions for judicial review or other actions challenging permits, amendments, license, arbitration, action, certificate, or inspection that are pending on or after the effective date.

The full text of the program and/or plan amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov.*

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., MDT. on August 22, 2023. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an

opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program and/or AML plan amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment.

We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 926

State regulatory program approval, State-federal cooperative agreement, Required program amendments.

David A. Berry,

Regional Director, Unified Regions 5, 7–11.

[FR Doc. 2023–16848 Filed 8–4–23; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

[SATS No. MT–043–FOR; Docket ID: OSM–2023–0008; S1D1S SS08011000 SX064A000 231S180110; S2D2S SS08011000 SX064A000 23XS501520]

Montana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Montana regulatory program (hereinafter, the Montana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). During the 2023 legislative session, the Montana legislature passed Senate Bill 392 (SB 392), amending the Montana Strip and Underground Mine Reclamation Act (MSUMRA) as well as the Montana Code Annotated (MCA). Accordingly, Montana submitted this proposed amendment to OSMRE on its own initiative. Montana's proposal adds a provision for the equal application of court costs to the prevailing party in contested case proceedings by a court or administrative agency that issues a decision. The proposal also amends the MCA to reference the equal application of court costs in section1. Finally, the proposal includes codification instructions, a severability clause, an effective date, and an applicability statement. This document gives the times and locations that the Montana program and this proposed amendment to the program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., M.D.T, September 6, 2023. If requested, we may hold a public hearing or meeting on the amendment on September 1, 2023. We will accept requests to speak at a hearing until 4:00 p.m., M.D.T. on August 22, 2023.

ADDRESSES: You may submit comments, identified by SATS No. MT–043–FOR, by any of the following methods:

- *Mail/Hand Delivery:* OSMRE, Attn: Jeffrey Fleischman, P.O. Box 11018, 100 East B Street, Room 4100, Casper, Wyoming 82602.
- *Fax:* (307) 261–6552.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID: OSM–2023–0008. If you would like to submit comments, go to *http://www.regulations.gov.* Follow the instructions for submitting comments.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than the ones listed above will be included in the docket for this rulemaking and considered.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Montana program, this amendment, a listing of any scheduled public hearings or meetings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Casper Field Office or the full text of the program amendment is available for you to read at *www.regulations.gov.*

Attn: Jeffrey Fleischman, Field Office Director, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82602, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov*

In addition, you may review a copy of the amendment during regular business hours at the following location:

Attn: Dan Walsh, Mining Bureau Chief, Coal and Opencut Mining Bureau, Department of Environmental Quality, P.O. Box 200901, Helena, MT 59601–0901, Telephone: (406) 444–6791, Email: *dwalsh@mt.gov*

FOR FURTHER INFORMATION CONTACT:
Attn: Jeffrey Fleischman, Field Office Director, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82602, Telephone: (307) 261–6550, Email: *jfleischman@osmre.gov*

SUPPLEMENTARY INFORMATION:

I. Background on the Montana Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Montana Program

Subject to OSMRE's oversight, section 503(a) of SMCRA permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its approved, State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with SMCRA and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7).

On the basis of these criteria, the Secretary of the Interior approved the Montana program on October 24, 1980. You can find background information on the Montana program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Montana program in the October 24, 1980, **Federal Register** (45 FR 70445). You can also find later actions concerning the Montana program and program amendments at 30 CFR 926.25.

II. Description of the Proposed Amendment

By letter dated June 22, 2023 (Administrative Record No. MT–043–01), Montana sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). We found Montana's proposed amendment to be administratively complete on June 27, 2023. Montana submitted this proposed amendment to us, of its own volition, following the passage of Montana Senate Bill 392 (SB 392) during the 2023 legislative session. SB 392 amends the MSUMRA as well as § 82–4–251 and § 82–4–252 of the MCA. SB 392 also adds four contingencies that apply to the proposed amendments.

Under section 1 of SB 392 Montana proposes to add a provision to MCA, section 1, for the equal application of court costs to the prevailing party in contested case proceedings by a court or administrative agency that issues a decision pursuant to § 82–4–2. This proposed section allows that a court or administrative agency may award the prevailing party reasonable costs of litigation, including filing fees, attorney fees, and witness costs. Under this proposal a court or administrative agency may not consider the identity of the party when awarding costs. This includes the permittee, permit applicant, agency, public interest litigant, or other party to the action. The proposal applies equally to all parties in an action and places the burden of proof and persuasion for awarding court costs on the requesting party. SB 392 does not state where section 1 will be codified in the MCA. This will be done by the legislature later; however, section 1 will be an integral part of the MCA.

Next, the proposal amends § 82–4–251(7) and § 82–4–252(5) to reference the equal application of court costs in section 1. § 82–4–251(7), which discusses the awarding of court costs, strikes out the word ''Whenever'' and adds the language ''Subject to the provisions of [section 1], whenever . . .''. § 82–4–252(5), which also discusses the awarding of court costs, strikes out the language ''. . . to any party whenever the court determines that the award is appropriate . . .'' and adds ''. . . pursuant to [section 1] . . .''.

Lastly, SB 392 adds four contingencies to section 1 and the proposed amendments to § 82–4–251 and § 82–4–252. The contingencies will not be codified into the MCA but apply to section 1 as proposed and the amended sections of the MCA. Section 4 of SB 392 contains codification instructions which state that [section 1] is intended to be codified as an integral part of § 82–4–2 and the provisions of § 82–4–2 apply to [section 1]. Section 5 is a severability clause and states that if a part of SB 392 found invalid, any part(s) found valid will remain in effect. Section 6 of SB 392 is an effective date, which states that the act is effective on passage and approval. Lastly, section 7 of SB 392 is an applicability clause, which states that SB 392 applies to court actions filed on or after the effective date of SB 392.

The full text of the program and/or plan amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov.*

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., MDT. on August 22, 2023. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program and/or AML plan amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 926

State regulatory program approval, State-federal cooperative agreement, Required program amendments.

David A. Berry,

Regional Director, Unified Regions 5, 7–11.

[FR Doc. 2023–16849 Filed 8–4–23; 8:45 am]

BILLING CODE 4310–05–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 14 and 64

[CG Docket Nos. 23–161, 10–213, 03–123; FCC 23–50; FR ID 157623]

Access to Video Conferencing

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) proposes to amend its rules to ensure that interoperable video conferencing services (IVCS) are accessible to people with disabilities and to facilitate the integration and appropriate use of telecommunications relay services (TRS) with video conferencing. These amendments are proposed to meet the need for people with disabilities to participate fully in video conferences, a technology that appears to have permanently altered the norms of modern communication in the workplace, healthcare, education, social interaction, and civic life.

DATES: Comments are due September 6, 2023. Reply comments are due October 6, 2023.

ADDRESSES: You may submit comments, identified by CG Docket Nos. 23–161, 10–213, and 03–123 by either of the following methods:

- *Federal Communications Commission's Website: https://www.fcc.gov/ecfs/filings.* Follow the instructions for submitting comments.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* document FCC 23–50 at *https://docs.fcc.gov/public/attachments/FCC-23-50A1.pdf.*

FOR FURTHER INFORMATION CONTACT: William Wallace, Disability Rights Office, Consumer and Governmental Affairs Bureau, at 202–418–2716, or *William.Wallace@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking, document FCC 23–50, adopted on June 8, 2023, released on June 12, 2023, in CG Docket Nos. 23–161, 10–213, and 03–123. Also, this document has a companion document published at 88 FR 50053, August 1, 2023. The full text of document FCC 23–50 is available for public inspection and copying via the Commission's Electronic Comment Filing System (ECFS).

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530.

Ex Parte Rules. This proceeding shall be treated as a permit-but-disclose proceeding in accordance with the Commission's *ex parte* rules. 47 CFR 1.1200 *et seq.* Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b) of the Commission's rules. In proceedings governed by § 1.49(f) of the Commission's rules or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize

themselves with the Commission's *ex parte* rules.

Synopsis

Background

Since the March 2020 outbreak of the COVID–19 pandemic in the United States, video conferencing has grown from a niche product to a central pillar of our communications infrastructure. In early 2020, after governments, businesses, and schools adopted social distancing requirements, organizations, families, and individuals turned to video conferencing as a work-around. Use of video conferencing increased exponentially, becoming a significant part of the technology solution replacing in-person meetings, conference calls, and traditional classroom instruction.

The new social interaction paradigm occasioned by the pandemic appears to have permanently altered the norms of modern communication in the workplace, healthcare, education, social interaction, civic life, and more. The pandemic amplified and accelerated the reality that much of Americans' lives take place online using an increasing variety of connected devices. For millions of Americans, video conferencing has become a mainstay of their business and personal lives.

With the growing use of video conferencing has come heightened concern about accessibility. Small screens make it difficult for users who are deaf or hard of hearing to identify visual clues, such as when a colleague is about to speak. When automatic captions are provided on video conference platforms, the quality and timeliness of the transcription varies widely. In a 2021 survey of 330 people with vision disabilities, approximately 57% of respondents found telehealth to be inaccessible in some way. Further, users who are blind or have limited vision describe struggles to find and toggle volume controls.

In recent years, various accessibility features have been introduced by a number of video conferencing providers. Depending on the platform, these features may include screen reader and braille display support, a choice of third-party live captioning or synchronous automatic captioning, multi-pinning features, and spotlighting a speaker so that all participants know who is speaking. Some services also offer keyboard accessibility features, high-contrast visual elements, customizable notifications, verbosity controls, and other accessibility innovations.

However, the accessibility of video conferencing services remains limited for many users. In its February 2022 recommendations to the Commission, the Disability Advisory Committee highlighted the inconsistent performance of video conferencing providers in making their platforms accessible to people who are deaf, hard of hearing, or deafblind. Commenters also point out that users with disabilities often are not in a position to dictate what video conferencing service the host of the conference should use. For example, a patient who is deaf may not be able to obtain healthcare because the doctor's telehealth conferencing platform does not enable an effective connection to a sign language interpreter or VRS. A student who is blind may be unable to fully participate in a remote class discussion if information provided through a share-screen feature is not accessible to screen readers. In these and other scenarios, a person with a disability often has no opportunity to request a different, accessible video conferencing system.

Under the Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA), Public Law 111–260, providers of advanced communications services (ACS) and manufacturers of equipment used for ACS must make such services and equipment accessible to and usable by people with disabilities, unless these requirements are not achievable. 47 U.S.C. 617(a)(1), (b)(1). Service providers and manufacturers may comply with these provisions either by building accessibility features into their services and equipment or by using third-party applications, peripheral devices, software, hardware, or customer premises equipment (CPE) that are available to individuals with disabilities at nominal cost. 47 U.S.C. 617(a)(2), (b)(2). If accessibility is not achievable through either of these means, then manufacturers and service providers must make their products and services compatible with existing peripheral devices or specialized CPE commonly used by people with disabilities to achieve access, subject to the achievability standard. 47 U.S.C. 617(c). The Communications Act of 1934, as amended (the Act), defines *advanced communications services* as: (1) interconnected Voice over internet Protocol (VoIP) service; (2) non-interconnected VoIP service; (3) electronic messaging service; (4) interoperable video conferencing service; and (5) any audio or video communications service used by inmates for the purpose of communicating with individuals outside the correctional institution where the inmate is held, regardless of technology used. 47 U.S.C. 153(1). *Interoperable video conferencing service,* in turn, is defined as a service that provides real-time video communications, including audio, to enable users to share information of the user's choosing. 47 U.S.C. 153(27).

In the Report and Order in document FCC 23–50, the Commission revisits its previously stated views regarding the interpretation of the statutory term *interoperable video conferencing service.* The Commission concludes that part 14 of its rules applies to all services and equipment that meet the statutory definition of *interoperable video conferencing service, i.e.,* all services and equipment that provide real-time video communications, including audio, to enable users to share information of the user's choosing.

TRS and Video Conferencing. Enacted in 1990, Title IV of the Americans With Disabilities Act, codified as section 225 of the Act, directs the Commission to ensure that interstate and intrastate telecommunications relay services are available, to the extent possible and in the most efficient manner, to eligible users in the United States. 47 U.S.C. 225(b)(1). *TRS* are defined as telephone transmission services enabling such persons to communicate by wire or radio in a manner that is functionally equivalent to the ability of a person without hearing or speech disabilities to communicate using voice communication services. 47 U.S.C. 225(a)(3).

There are currently three forms of internet-based TRS: Video Relay Service (VRS) allows people with hearing or speech disabilities who use sign language to communicate with voice telephone users through video equipment; Internet Protocol Relay Service (IP Relay) allows an individual with a hearing or speech disability to communicate with voice telephone users by transmitting text via the internet; and Internet Protocol Captioned Telephone Service (IP CTS) permits a person with hearing loss to have a telephone conversation while reading captions of what the other party is saying on an internet-connected device.

TRS Fund. The provision of internet-based TRS is supported by the TRS Fund. In addition, the TRS Fund supports interstate use of certain non-internet-based relay services, which are provided through state TRS programs. Entities required to make contributions to the TRS Fund include providers of telecommunications service, interconnected VoIP service, and non-interconnected VoIP service.

Disability Advisory Committee Report on TRS and Video Conferencing. The structure of the Commission's TRS program reflects the fact that, historically, most people have used wireline or wireless telephone networks to communicate remotely by voice. Thus, North American Numbering Plan (NANP) telephone numbers are used to route calls between TRS users and hearing people, and the provision of TRS, to date, has typically included a voice-only telephone call, with originating and terminating NANP numbers. To address concerns about the inaccessibility of video conferencing platforms, the Commission requested the Disability Advisory Committee to study the use of TRS on IVCS platforms. In a report delivered in February 2022, the committee states:

> [I]t is impossible for users of most video conferencing platforms and most TRS providers to natively interconnect their preferred TRS provider to video conferencing platforms. Typically, TRS users can only interconnect their preferred TRS provider to a video conferencing platform by dialing in via the public switched telephone network.

Such a dial-in connection is often unavailable. Further, when a dial-in connection to a video conference is available, a TRS user may encounter multiple difficulties. For example, the user must use two separately connected devices—one to participate in the video portion of the conference and the other to communicate with the TRS provider's communications assistant (CA), who is only connected to the video conference via an audio-only dial-in connection. As a result, the user must navigate multiple user interfaces, which can cause confusion, fatigue, and other barriers to full participation in a video conference. If multiple TRS users join the conference, with each user having a double presence as the user's video image and a CA's voice-only icon, the result can increase the overall cognitive load for video conference hosts and participants to process discussion and facilitate shared dialogue. Further, the CA's audio-only connection may result in poor audio quality, causing errors in interpretation or captioning. The committee also explains that it is not clear whether the Commission's rules allow other methods of linking a TRS CA to a video conference. Since the committee's recommendations were published, one VRS provider has reported that it now offers a means of integrating its provision of VRS with one video conferencing platform.

For these reasons, the Disability Advisory Committee recommends that the FCC resolve these issues by: facilitating a technical mechanism for TRS providers to natively interconnect TRS services, including video, audio, captioning, and text-based relay to video conferencing platforms; ensuring that users can seamlessly initiate TRS from the provider of their choice on any video conferencing platform; addressing the integration of CAs and the overall accessibility challenges of videoconferencing platforms; and clarifying the legal ability of TRS providers to seek compensation for service provided for video conferences from the TRS fund.

Proposed Rules

The Commission proposes to amend its rules to improve the accessibility of video conferencing, whether used for work, education, healthcare, entertainment, or other activities. The proposals in this document are applicable to those services that fit the statutory definition of *interoperable video conferencing service. See* 47 U.S.C. 153(27). In this document, when the Commission refers to *video conferencing* or *video conferences,* it means video conferencing or video conferences that involve the use of an *interoperable video conferencing service,* as defined.

First, to address the integration of TRS CAs and the overall accessibility challenges of videoconferencing platforms, the Commission proposes to adopt additional performance objectives for the accessibility of interoperable video conferencing services. Specifically, the Commission proposes that such performance objectives include the provision of speech-to-text (*e.g.,* captioning of all voice communications in a video conference) and text-to-speech; and enable the use of sign language interpreting. The Commission seeks comment on whether additional amendments are needed to ensure that video conferencing is accessible. The Commission also seeks comment on whether technical standards are available or could be fashioned for use as safe harbors, whereby certain performance objectives for IVCS can be satisfied by providing access to relevant forms of TRS.

Second, the Commission proposes to amend part 64 of its rules to provide that the TRS Fund can be used to support the provision of TRS for video conferencing users—whether or not the video conferencing platform can be accessed via a NANP telephone call. In addition, the Commission proposes certain modifications to its rules to specify the conditions under which the TRS Fund will support the provision of TRS with video conferencing.

Amending Part 14 To Improve the Accessibility of Video Conferencing

Performance Objectives. Section 716 of the Act directs the Commission to adopt performance objectives to ensure the accessibility, usability, and compatibility of ACS. 47 U.S.C. 617(e)(1)(A). To implement this requirement, the Commission in 2011 adopted general performance objectives specifying that input, control, and mechanical functions are locatable, identifiable, and operable by people with disabilities and that all information necessary to operate and use the product is available to people with disabilities. For example, ACS must be operable without hearing, which is defined to mean that it must provide at least one mode that does not require user auditory perception. 47 CFR 14.21(b). These performance objectives provide a definition of *accessible* for purposes of the Part 14 rules. Other performance objectives define *usable* and *compatible.* 47 CFR 14.21(c), (d). These general performance objectives are applicable to IVCS as well as other types of ACS.

The Commission believes that the performance objectives in part 14 of its rules have encouraged innovative and effective approaches to achieve accessibility for covered equipment and services. However, given the seismic shift in how society communicates, and based on this proceeding's record and the Disability Advisory Committee Report, the Commission seeks comment on whether to amend the rules to define more specific objectives for making IVCS accessible. The Commission notes that some IVCS providers have added accessibility features to their products in response to consumer need during the COVID–19 pandemic. The Commission seeks comment on the effectiveness of these features in providing accessibility, the extent of their availability, their ease of use, and how they could be improved. The Commission also seeks comment on what other features may be necessary to make IVCS accessible and how the current performance objectives could be modified or supplemented to ensure that such features are provided if achievable.

Disability Advisory Committee Recommendations. As the Disability Advisory Committee explained, without the ability to have other participants' audio communications converted to text or sign language, as appropriate, and to have their own text or sign language communications converted to speech, a person who is deaf or hard of hearing or has a speech disability may not be able

to effectively participate in a video conference. The Committee recommends that the Commission ensure, at a minimum, that video conferencing platforms: include built-in closed captioning functionality that is available to all users, including to users with free accounts if the platform provides such accounts; fully integrate support for TRS CAs, including video, audio, captioning, and text communication; and allow users, including CAs, to control the activation and customize the appearance of captions and video interpreters, including caption activation, size, color, background, layout, and positioning, pinning and multi-pinning, side-by-side views, hiding non-video participants, including American Sign Language (ASL) interpreters, Certified Deaf Interpreters, and other interpreters, and cued language transliterators, and exercise this control on their own clients without reliance on video conference hosts.

The Commission proposes to amend the performance objectives in part 14 of its rules to address these recommendations and promote innovative future solutions for making IVCS accessible. Consistent with section 716 of the Act, the proposals would permit IVCS providers to choose whether to satisfy their accessibility obligations by including certain features as native applications or by using third party applications, peripheral devices, software, hardware, or CPE that is available to the consumer at nominal cost and that individuals with disabilities can access. 47 U.S.C. 617(b)(2)(B). *Nominal cost* means that any fee for third-party software or hardware accessibility solutions shall be small enough so as to generally not be a factor in the consumer's decision to acquire a product or service that the consumer otherwise desires. *Implementing the Provisions of the Communications Act of 1934, as Enacted by the Twenty-First Century Communications and Video Accessibility Act of 2010,* published at 76 FR 82353, December 30, 2011. IVCS providers must maintain records of their efforts to ensure that their services and products are accessible, 47 CFR 14.31(a), and the Commission's rules do not provide an exemption from this requirement for service providers who rely on third-party applications or equipment to achieve accessibility.

Captions. The Commission proposes to adopt, as a performance objective specific to IVCS, the provision of captions for the audio communications in video conferences. For people who are deaf or hard of hearing, a lack of captions can make meaningful interaction impossible. Some video conferencing platforms offer captions, which are typically provided via automatic speech recognition (ASR). However, according to the Disability Advisory Committee, captions are not available on all platforms, or on all video conferences for platforms that do provide them, and where they are available they may be of insufficient quality to ensure functional equivalence.

Automatic captioning, when available, sometimes produces incomplete or delayed transcriptions, while the delays inherent in live captioning can lead to cognitive overload as users try to follow poorly synchronized visual and textual conversations. In addition, because voice conversations go quickly and it may be difficult to immediately identify who is speaking, video conferences may cause some people who are deaf or hard of hearing to lose vital portions of voice communications. Finally, some research indicates that ASR technology may show algorithmic bias in the accuracy with which it transcribes voices, particularly in the transcription of certain speakers.

The Commission proposes to amend § 14.21 of its rules to make clear that captioning is an essential component of accessibility in the context of IVCS. Section 14.21(b)(2)(iv) of the Commission's rules currently specifies that accessibility includes providing auditory information through at least one mode in visual form and, where appropriate, in tactile form. 47 CFR 14.21(b)(2)(iv). As noted above, however, the record indicates that not every IVCS offers captioning, and that where captioning is offered, the quality is often uneven. Therefore, the Commission proposes to amend § 14.21(b)(2)(iv) of its rules to read (with proposed new text shown in bold):

Availability of auditory information. Provide auditory information through at least one mode in visual form and, where appropriate, in tactile form. **For interoperable video conferencing services, provide at least one mode with captions that are accurate and synchronous. The accuracy and latency of such captions should be at minimum comparable to that provided on TRS Fund-supported captioned telephone services.**

The Commission seeks comment on this proposal. Does this language provide an appropriate level of specificity, given, on the one hand, the need for effective guidance on what accessibility requires, and on the other, the need to allow flexibility in implementation and innovative solutions, and to avoid mandatory technical standards? The Commission has a pending proceeding on quantifying minimum standards for the quality of captions provided by TRS Fund-supported captioned telephone services and establishing methods of measuring caption quality. Pending completion of that proceeding, this proposed performance objective states that caption quality should be generally comparable to that offered by TRS Fund-supported services. In the future, with the adoption of metrics for captioned telephone services by the Commission, such metrics could serve as a safe-harbor technical standard for IVCS as well.

Is this level of quality sufficient to provide a functionally equivalent experience for all users, including users of color or users with accents? Alternatively, the Commission invites comment on the extent to which current performance objectives, such as § 14.21(b)(2)(i) of its rules, already require that IVCS provide an appropriate level of caption quality. How can the FCC promote improvements in ASR technology to address any existing algorithmic bias?

In some instances, the host of a video conference may prefer (or have a legal obligation) to use another captioning service—be it live captioning or ASR—rather than the IVCS provider's captioning feature. According to the Disability Advisory Committee:

> When out-of-band interpreters, transliterators, or captioners can be secured, many video conferencing platforms do not provide sufficient accessibility features to ensure that they can be integrated properly in a video conference to ensure accessibility. Some video conferencing platforms have problems properly joining and integrating caption streams to be displayed on streams, requiring users to open a separate web browser or application to view captions.

To address this concern, the Commission seeks comment on whether to specify that IVCS enable the use of alternative captioning methods, such as Communication Access Realtime Translation (CART). CART is the instant translation of the spoken word into English text using a stenotype machine, computer, and realtime software. Similarly, should IVCS be compatible with TRS Fund-supported captioning, so that such captioning can be displayed in a video conference if requested by a TRS user? Is there a commonly used technology that would enable the display of, *e.g.,* CART or IP CTS captioning to all participants in a video conference? Would the adoption of such a performance objective be consistent with section 716(b)(2) of the Act, 47

U.S.C. 617(b)(2), which allows covered service providers to meet their accessibility obligations either natively or by using third party applications or equipment?

Text-to-Speech. To ensure that IVCS is operable by people with disabilities who need to communicate by text, the Commission proposes to amend 47 CFR 14.21(b)(1)(ix), which specifies that ACS be operable in at least one mode that does not require user speech, to read (with proposed new text shown in bold):

Operable without speech. Provide at least one mode that does not require user speech. **For interoperable video conferencing services, provide at least text-to-speech functionality.**

The Commission seeks comment on this proposal. Would text-to-speech and captions, along with compatibility with refreshable braille displays or other peripheral devices, make IVCS accessible for people who are deafblind and for people with speech disabilities who cannot or do not use Speech-to-Speech relay service (STS)? STS is a form of TRS that allows individuals with speech disabilities to communicate with voice telephone users through the use of specially trained CAs who understand the speech patterns of persons with speech disabilities and can repeat the words spoken by that person. 47 CFR 64.601(41). STS is currently provided only through state-certified relay service programs. Should the Commission also specify that IVCS support the use of IP Relay, and would such a specific performance objective be consistent with the flexible compliance approach permitted by section 716(b)(2) of the Act? Is there an effective means for users to connect with and use IP Relay in video conferences?

Sign Language Interpreting. The Commission also proposes to adopt, as a performance objective, that IVCS enable the provision of sign language interpreting, such as through a third-party interpreting service or a VRS provider. According to the Disability Advisory Committee, many video conferencing platforms do not provide sufficient accessibility features to ensure that interpreters can be integrated properly in a video conference. Further, at present, video conferencing platforms generally are not configured to allow the connection of VRS CAs to a video conference, except through a voice-only dial-in connection. The need to connect a VRS CA through a dial-up connection poses multiple difficulties for the user, including the need to use two separately connected devices, splitting attention between the two in a way that appears to fall short of functionally equivalent participation in a video conference. However, some companies are developing ways to enable VRS CAs to have a video presence on a video conferencing platform, enabling a solution to these problems. A VRS provider, Sorenson Communications, has made available to its customers an application that allows its CAs to participate in a Zoom conference call.

To provide guidance on how to make video conferencing accessible to people who use sign language, the Commission proposes to add a new performance objective to § 14.21 of its rules to specify that accessibility for IVCS includes enabling an effective video connection for sign language interpreters, including VRS CAs, so that they can be pinned and viewed by those who use such services. The Commission seeks comment on this proposal and its costs and benefits, and also seeks comment on the following language for this proposed performance objective:

Sign language interpretation. Interoperable video conferencing services shall enable the use of sign language interpretation, including the transmission of user requests for sign language interpretation to providers of video relay service and other entities and the provision of sufficient video quality to support sign language communication.

To ensure that providers of video remote interpreting (VRI) and VRS can connect with an IVCS provider's platform, should the Commission also specify in this performance objective that IVCS providers make technical specifications available on their websites, indicating how to make use of the relevant capabilities? Are there other forms of visual communication that this rule should cover for use on video conferences? For example, Cued English uses hand shapes, hand placements, and non-manual signals on the mouth to provide a transliteration of spoken English for some individuals with hearing disabilities. How would requiring the ability to connect interpreters or transliterators for additional forms of visual communication (if procured, *e.g.,* by the host or organizer of a video conference) affect the costs and benefits of this proposed rule?

The Commission also seeks comment on whether additional performance objectives should be specified for IVCS to address other accessibility concerns. For example, are the current performance objectives in part 14 of the Commission's rules sufficient to ensure that people with disabilities other than hearing and speech disabilities can effectively participate in video conferences?

User Interface Controls. The Disability Advisory Committee and some commenters raise a concern that video conferencing platforms do not provide certain user interface controls needed for accessibility. To address these concerns, the committee recommends that the Commission ensure that such platforms:

Allow users, including CAs, to control the activation and customize the appearance of captions and video interpreters, including caption activation, size, color, background, layout, and positioning, pinning and multi-pinning, side-by-side views, hiding non-video participants, including ASL interpreters, [Certified Deaf Interpreters], other interpreters, and cued language transliterators, and exercise this control on their own clients without reliance on video conference hosts.

Section 14.21(b) of the Commission's rules generally requires that the control functions necessary for a user to operate a covered service or product be accessible. The Commission invites comment on the extent to which the existing performance objectives already require control functions that would address the committee's recommendation. If not, would adding a performance objective such as the following effectively and appropriately address those concerns?

Interoperable video conferencing services shall provide user interface control functions that permit users to adjust the display of captions, speakers and signers, and other features for which user interface control is necessary for accessibility.

Should the Commission identify additional kinds of user interface controls that are necessary for accessibility? Commenters are invited to recommend language for performance objectives that would provide appropriate guidance in this area.

Costs and benefits. The Commission seeks comment on the costs and benefits of the above proposals. What benefits would result, and what costs would IVCS providers and other affected entities incur to: enable captioning of video conferences; provide text-to-speech capabilities; enable a video connection for sign language interpreters and VRS CAs; improve user interface controls; and address other possible performance objectives discussed above or in responsive comments?

How should the Commission quantify such incremental costs? How should it compare those costs with the benefits to IVCS users? Are there cost savings the Commission should consider—such as costs that could be incurred by video conference hosts or participants to provide captioning in the absence of

platform-provided captioning? Further, IVCS providers may view accessibility not only as a public obligation, but also as a market opportunity. The Commission seeks comment on this view.

In addition to describing and (where possible) quantifying the benefits that would result from meeting all the performance objectives proposed above, the Commission invites comment on the extent to which particular performance objectives are achievable, either at present or in the foreseeable future. The Commission stresses that each of the amendments proposed above, if adopted, would remain subject to the general condition that a provider or manufacturer need not meet the objective if it is not achievable to do so. Therefore, the Commission may adopt new or modified performance objectives even if they are not immediately achievable for every provider. However, the Commission can better assess the likely benefits of these proposals if there is evidence as to whether or not a performance objective is likely to be achievable, for at least some covered entities, within the foreseeable future.

Legal Authority. The Commission believes the Act provides legal authority for the above proposals. Section 716 of the Act requires providers of ACS and manufacturers of equipment used with ACS, including interoperable video conferencing service, to make their services and equipment accessible to and usable by individuals with disabilities, unless that is not achievable. The Act directs the Commission, in broad terms, to adopt implementing regulations that, among other things, include performance objectives to ensure the accessibility, usability, and compatibility of advanced communications services and determine the obligations under this section of manufacturers, service providers, and providers of applications or services accessed over service provider networks. 47 U.S.C. 617(a)(1), (b)(1). Further, whenever that requirement is not achievable, a service provider shall ensure that its service is compatible with existing peripheral devices or specialized customer premises equipment commonly used by individuals with disabilities to achieve access, unless this requirement too is not achievable. 47 U.S.C. 617(c). A manufacturer of equipment used for IVCS is similarly required to make its products accessible to and usable by people with disabilities, unless it is not achievable to do so. The Commission believes its proposals fall within this broad grant of authority and are consistent with other provisions of section 716 of the Act, including the allowance for flexible implementation through either native or third-party applications, the prohibition on mandating technical standards, and the condition that compliance is not required if it is not achievable. 47 U.S.C. 617(a)(1), (b)(1), (e)(1)(D). The Commission seeks comment on this analysis.

The Commission also seeks comment on whether there are other sources of authority supporting the above proposals. For example, in 2007 the Commission found that it had authority, ancillary to section 225 of the Act, to require interconnected providers of VoIP service to provide access to TRS. Could the Commission also find that it has authority ancillary to section 225, or other provisions of the Act, to require video conferencing service providers to provide TRS access to interoperable video conferences? If so, what would be the bases for such a finding?

Safe Harbor Technical Standards. Section 716 of the Act provides that the Commission shall not adopt mandatory technical standards for ACS accessibility. However, the Commission may adopt technical standards as a safe harbor for such compliance if necessary to facilitate the manufacturer's and service providers' compliance. 47 U.S.C. 617(e)(1)(D). The Commission therefore seeks comment on whether technical standards are available (or in development)—*e.g.,* WebRTC or portions thereof—that could serve as safe harbors for IVCS compliance with one or more applicable performance objectives, including the additional performance objectives proposed above, whereby a performance objective can be satisfied if an IVCS complies with the technical standard. WebRTC, short for Web Real-Time Communications, is an open-source internet standard that allows for real-time video communications through a user's internet browser, foregoing the need for plug-ins or standalone third-party software. On January 26, 2021, the World Wide Web Consortium and the internet Engineering Task Force announced WebRTC as an official standard. Although designed as a tool for internet browsers, WebRTC applications are now also being developed for mobile and Internet of Things devices.

Any commenter who proposes that a technical standard be recognized as a safe harbor is invited to discuss the costs and benefits of the proposal, and how the Commission would verify compliance with the standard. In general, are there costs or benefits to innovation of recognizing certain technical standards as safe harbors? Given the pace of technological innovation, how often should a safe harbor be updated, or should it be designated to expire after a date certain?

The Commission also seeks comment on how it can assist with or promote the development of safe harbor technical standards in this area. For example, there are numerous IVCS providers, each with a specific technology configuration, and there are multiple VRS providers as well. Would substantial costs be saved if all companies adhered to a common technical standard for integrating interpreters and VRS CAs into video conferences? How could the Commission facilitate the development of a useful standard?

Providing TRS in Video Conferences

Responding to the Disability Advisory Committee's recommendations, the Commission proposes to amend its rules to clarify that the integrated provision of TRS to enable functionally equivalent participation in video conferences can be supported by the Interstate TRS Fund. Just as the TRS Fund has long been used to support the provision of TRS with audio-only teleconferencing, the Commission believes it is necessary and appropriate, as a general matter, that the TRS Fund be used to support the provision of TRS with video conferencing.

The Commission tentatively concludes that section 225 of the Act authorizes the Commission to support the integrated provision of TRS in video conferences, without any need for either the TRS user or the CA to place a dial-up, voice-only call to the video conferencing platform. By *integrated provision of TRS* in a video conference, the Commission means an arrangement whereby communication between the CA (or automated equivalent) and video conference participants, whether by voice, text, or sign-language video, takes place on the video conferencing platform (where it can be available to all participants), rather than through a separate dial-up connection. The Act defines telecommunications relay services as: telephone transmission services that provide the ability for an individual who is deaf, hard of hearing, deaf-blind, or who has a speech disability to engage in communication by wire or radio with one or more individuals, in a manner that is functionally equivalent to the ability of a hearing individual who does not have a speech disability to communicate using voice communication services by wire or radio. 47 U.S.C. 225(a)(3) (emphasis added). Applying this

definition, the Commission tentatively concludes that when the provision of a relay service is integrated with a video conferencing platform (without using a dial-up, voice-only connection), the provision of such service to an eligible TRS user is a telephone transmission service that enables communication by wire or radio in a manner that is functionally equivalent to the ability of a hearing individual who does not have a speech disability to communicate using voice communication services by wire or radio.

As indicated above, section 225 of the Act defines TRS in terms of its purpose—to enable people with hearing or speech disabilities to communicate by wire or radio in a manner that is functionally equivalent to how people without such disabilities use voice communication services. Both *radio communication* and *wire communication* are broadly defined in the Act as the transmission of writing, signs, signals, pictures and sounds of all kinds, including all instrumentalities, facilities, apparatus, and services (among other things, the receipt, forwarding, and delivery of communications) incidental to such transmission. 47 U.S.C. 153(40), (59). These definitions include wire or radio communication using internet Protocol. Further, the Commission believes that *interoperable video conferencing service,* which is defined to include audio communication, is appropriately characterized as a voice communication service for purposes of section 225 of the Act.

While *telephone transmission service* is not defined in the Act, the Commission has given this term a similarly broad interpretation. As the Commission explained in 2002, the use of this phrase to define TRS is constrained only by the requirement that such service provide a specific functionality, namely the ability to communicate by wire or radio in a manner functionally equivalent to voice communication. Further, section 225 of the Act directs the Commission to ensure that regulations prescribed to implement that section encourage, consistent with section 7(a) of the Act, the use of existing technology and do not discourage or impair the development of improved technology. 47 U.S.C. 225(d)(2). In its prior decisions authorizing new forms of TRS, the Commission has found that internet-based relay services are not limited to a specific technical configuration. For example, when finding IP CTS to be a compensable form of TRS, the Commission emphasized that the service could be initiated, set up, and provided in numerous ways, including using specific telephone equipment or IP-enabled devices, and various combinations of the public switched telephone network and IP-enabled networks. Similarly, when the Commission approved compensation for VRS, it noted that the service was under development using a number of equipment configurations. Further, the Commission has not interpreted *telephone transmission service* as requiring the use of telephone numbers. For example, VRS users were not assigned NANP numbers until 2008.

The Commission seeks comment on the foregoing tentative conclusion and interpretation of its authority under section 225 of the Act. Among other things, comment is sought on whether anything in section 225 or elsewhere in the Act indicates that the Commission's authority in this context is limited to making TRS available only with voice services that rely on the use of NANP telephone numbers. How could such a restrictive interpretation be squared with the broad language of the statutory definition of TRS?

Below, the Commission seeks comment on how to modify the Commission's TRS rules to facilitate such integration, ensure the appropriate use of VRS with video conferencing, and prevent waste, fraud, and abuse. First, the Commission proposes and seeks comment on measures that specifically address the integration of VRS with video conferencing. Then, it seeks comment on whether additional rule amendments are needed to specifically address the integration of other types of TRS with video conferencing. Finally, the Commission proposes to amend certain generally applicable TRS rules to address the integrated provision of TRS regardless of type.

Integrating the Provision of VRS With Video Conferencing

The Commission tentatively concludes that the integrated provision of VRS with video conferencing is often necessary to enable sign-language users to communicate in a functionally equivalent manner. By *integrated provision of VRS* in a video conference, the Commission means an arrangement whereby a CA is included as a participant in the video conference and all communication between the CA and the participants takes place on the video conferencing platform rather than through a separate connection. First, the only alternative for connecting a VRS CA to a video conference—using a dial-up, voice-only connection—is often unavailable. Assuming the video conferencing platform allows a dial-up connection, it is usually the video conference organizer or host who determines whether a dial-up option is provided. Similarly, the conference organizer or host may or may not hire a sign language interpreter to provide communication assistance for a video conference. Second, the need to connect a VRS CA through a dial-up connection poses multiple difficulties for the user. For example, the VRS user must navigate between two separately connected devices and user interfaces—one to participate in the video portion of the conference and the other to communicate with the VRS CA—and this can cause confusion, fatigue, and other barriers to effective communication. In addition, the CA who, unlike other participants, is limited to an audio connection, is unable to read documents or other text that may be displayed, interpret facial expressions, or attend to other visual cues on which video conference participants often rely for effective communication. The Commission seeks comment on this tentative conclusion.

The active development and deployment of technological solutions for the integrated provision of VRS in a video conference has crystallized a number of issues regarding the application of the TRS rules to such integration. Therefore, the Commission proposes to amend its rules, as set forth below, to facilitate such integration, ensure the appropriate use of VRS with video conferencing, and prevent waste, fraud, and abuse.

In addition, the Commission invites the submission of comments describing in detail any ongoing efforts by VRS providers and IVCS providers to enable the integration of VRS with IVCS, and how far their development has progressed. Comment is sought on the extent to which the integration methods and technologies currently being developed or deployed are usable (or can be made usable) with more than one video conferencing platform or more than one VRS provider. What steps can the Commission take to encourage or assist with the development of standardized or open-architecture solutions, so that IVCS providers, TRS providers, and the TRS Fund do not needlessly incur duplicative costs to support multiple solutions unique to each video conferencing platform and VRS provider? What changes in the TRS interoperability rule, or other Commission rules, would promote wider availability of effective technical solutions in this area? To the extent that technological solutions are feasible, should the Commission not only

authorize, but also *require* VRS providers to provide VRS with IVCS on an integrated basis?

User Validation and Call Detail. To collect compensation from the TRS Fund, a VRS provider must validate that the person using a video connection to place or receive a VRS call is a registered VRS user. Ordinarily, a person's status as an eligible user is verified by means of the NANP telephone number from which or to which a call is placed. By contrast, video conference participants typically enter a video conference via the internet (*e.g.,* by clicking the link provided by the host of the video conference) without dialing from a line associated with a telephone number. As discussed earlier, while some video conferencing platforms may allow a participant to connect via a voice-only, dial-up connection, the availability of such a connection for a particular video conference is up to the conference host or organizer. Further, VRS users may connect to a video conference without first contacting their VRS provider. The Commission seeks comment on how VRS providers can most efficiently and effectively confirm a video conference participant's eligibility for VRS when the user has not joined the video conference by placing a call from a NANP telephone number.

For example, should the Commission amend its rules to specify that, to validate the integrated provision of VRS in a video conference, information may be entered in a video conferencing application by a registered user and transmitted by the IVCS provider to a VRS provider, along with a request to provide a CA? If so, what information should be provided? Would a user's NANP telephone number suffice—even though it is not actually being used to connect with the video conference? Or should the Commission require a log-in ID and password? Should the Commission allow the provision of integrated VRS in video conferences pursuant to an enterprise registration, and if so, would the telephone number associated with an enterprise videophone suffice for validating such use? Are there other methods of validation that should be permitted in the video conferencing context?

The Commission also seeks comment on how the rules should address video conferences that are initiated informally, without an advance invitation, by one person dialing the telephone number, entering an email address, pressing an icon or otherwise contacting one or more other parties using a service such as GoogleMeet or FaceTime. Are there currently available or in development any technologies for integrating a CA with this type of video conference? Do the existing TRS rules and procedures suffice to verify, for these kinds of video conferences, that the caller or called party is a registered VRS user? Would this scenario require any changes to the TRS rules?

In addition, the VRS provider will need to be able to collect and provide an appropriate call detail record to submit to the TRS Fund administrator. Because the rules may apply differently to video conferences in a number of respects, the Commission proposes to require that call detail records submitted by VRS providers identify, as such, video conferences in which VRS is provided on an integrated basis. What other information should the Commission require VRS providers to collect and submit to the TRS Fund administrator to identify, for billing purposes, the integrated provision of VRS in a video conference? What routing information is available for the TRS Fund administrator to verify the presence of the VRS user and the CA or CAs in a video conference? Are originating and terminating Uniform Resource Locators (URLs) needed, and if so, how can they be collected? Alternatively, is it sufficient to provide the user's phone number or log-in, in lieu of the originating URL? How would VRS providers comply with the requirement to employ an automated record keeping system to capture call record data? How would VRS providers and the TRS Fund administrator identify non-compensable international calls? How would VRS providers verify that, based on the parties involved, the provision of TRS in a video conference is eligible for TRS Fund compensation? For example, a video conference involving only VRS users does not require a CA to relay the conversation and so would not be eligible for TRS Fund compensation. In addition, comment is sought generally on what measures VRS providers should be required to take to prevent misuse of VRS or waste, fraud, and abuse of the TRS Fund in the context of video conferencing.

CA-Related Issues. There may be a number of situations in which more than one VRS CA participates in a video conference. This could occur, for example, if two or more participants send service requests to different providers. The Commission seeks comment on whether the TRS rules should apply differently in this respect to a video conference than to a teleconference. In a multi-party teleconference involving at least one hearing user, our rules do not restrict the number of different TRS providers whose services may be used by various parties to the call. Given that any VRS provided on an integrated basis will be available to all participants, are any restrictions warranted on the number of different providers who may provide VRS in a single video conference?

The Commission also seeks comment on whether to amend the rules to authorize a single VRS provider to assign multiple CAs for a video conference in certain circumstances (and to receive additional compensation from the TRS Fund for minutes involving multiple CAs). First, two or more VRS users may each request service from the same VRS provider on the same video conference. In an analogous teleconference where two or more users have connected through VRS, compensation would be paid for multiple calls—with each user's connection through a CA being treated as a separate call. However, in a video conference with integrated VRS, unlike a teleconference, it is possible for all participants to be served by one CA. In such cases, should the TRS Fund support the provision of a separate CA for each user, or, to prevent waste (and potential confusion among video conference participants), the number of CAs provided be limited, and if so, based on what criteria?

Second, in certain kinds of video conferences, it may be desirable for two CAs to participate in the call, working as a team—even if only one participant has requested VRS. Under the current TRS Fund compensation scheme, additional compensation is not paid to support multiple CAs in a teleconference if only one participant has connected through VRS. However, video conferences may often involve dynamic interaction among multiple participants. According to one ASL interpreting service, a team of two interpreters may be recommended based on the dynamics of the interactions and number of participants involved, for example, for highly interactive meetings, or legal requests, with multiple Deaf participants.

Should the Commission's rules be amended to allow a VRS provider to earn additional compensation for providing more than one CA in certain video conferencing scenarios, and if so, how should those situations be defined? For example, are there professional interpreter guidelines or best practices on which the Commission could rely that define when multiple ASL interpreters should be present at a meeting? The Registry of Interpreters for the Deaf, Inc., states that factors to be considered in deciding whether to

provide team interpreting include: the length and complexity of the assignment; unique needs of the persons being served; physical and emotional dynamics of the setting; and avoidance of repetitive stress injuries for interpreters. To what extent are guidelines for community interpreting applicable in the VRS context? For example, length of an assignment may be a less relevant factor for VRS because interpreters can be more efficiently substituted for one another when they do not need to be physically present at a meeting. Are there any situations where the TRS Fund should support *more* than two CAs from a single VRS provider?

The Commission proposes that, in the ordinary case, if the VRS user who requested service leaves a video conference, or is disconnected, before the session ends, then the billable period has ended and the CA should leave the video conference. In the context of an ordinary VRS call or conference call, if the TRS user is voluntarily or involuntarily disconnected from the call, he or she must initiate another call with a new CA. The Commission seeks comment on this proposal and on what, if any, exceptions should be allowed. For example, if other registered VRS users are participating in the same video conference, who were being assisted by the same CA, should the initial CA be permitted to stay on the video conference for a limited period to ensure continuity of service, and if so, for how long? Are other flexible alternatives available to ensure seamless VRS for other eligible users or ensure a smooth transition between CAs, while minimizing any risk of waste, fraud, or abuse? Are there any other issues that may arise when multiple VRS users and other participants are present in the same IVCS call, and how should they be resolved?

VRS CAs generally must stay on a call for a minimum of 10 minutes, after which they may be replaced by another CA. 47 CFR 64.604(a)(1)(v). The Commission seeks comment on whether to adjust this timeframe for the provision of VRS in video conferences. If so, what timeframe would be reasonable?

In addition, to ensure a seamless takeover between CAs from the same VRS provider during a video conference, is it desirable for a replacement CA to join the video conference and observe or acquire background information for some period of time before taking over from the first CA? If so, what would be a reasonable transition period? Is there a standard timeframe that VRS providers should adhere to, or should it be left to the discretion of the CAs or the VRS user? Are there professional guidelines or best practices that shed light on this question? Should a VRS provider be compensated for each CA's time while both the initial and replacement CAs are on the call? How can the Commission encourage uninterrupted VRS call takeovers during video conferences, while not unduly burdening the TRS Fund and Fund contributors?

Privacy Screen Rule. The Commission proposes to modify its rules to allow flexibility for VRS users and CAs to turn off video while participating in a video conference. The current rules prohibit a VRS CA from enabling a visual privacy screen or similar feature during a VRS call and require the CA to disconnect a VRS call if the caller or called party enables a visual privacy screen or similar feature for more than five minutes or is otherwise unresponsive or unengaged for more than five minutes. 47 CFR 64.604(a)(6). A *visual privacy screen* is defined as a screen or any other feature that is designed to prevent one party or both parties on the video leg of a VRS call from viewing the other party during a call. 47 CFR 64.601(a)(52). The Commission adopted this rule in 2011 as one of numerous measures aimed at halting the epidemic of fraud and abuse then plaguing the VRS program. The rule's stated purpose was to stop illicit schemes that result in calls running without any communication between the parties for the sole purpose of fraudulently billing the Fund.

In a multi-party video conference, however, a participant may turn off his or her video camera for various reasons that may not indicate lack of engagement with the discussion. For example, in some video conferences, the host may request that all participants turn off their videos unless speaking, to make it easier for participants who are deaf to view a sign language interpreter. Or, an interpreter may stop his or her video when a second interpreter is present and is interpreting a particular person's voice or signing. Further, on a video conference where one or more participants are speaking at length, participants who are deaf (like other participants) may choose to turn off their videos until it is their turn to speak.

The Commission proposes to allow VRS CAs to continue providing relay services integrated with a multi-party video conference when the VRS user who requested service has turned off his or her video connection for more than five minutes, as long as at least one other party is continuing to speak and the VRS user is still connected to the video conference. Under the proposed amendment, if five minutes elapse in which no party on a multi-party video conference is responsive or engaged in conversation, the VRS CA shall follow the current procedure, *i.e.,* announce that VRS will be terminated and leave the video conference. The Commission proposes to define *multi-party video conference* as a video conference with three or more participants, excluding VRS CAs and any other participant providing an accommodation for a participant. It also proposes to allow VRS CAs to turn off their video connections when taking turns relaying conversation with another VRS CA on a multi-party video conference. The Commission seeks comment on these proposals. Are there other steps that should be taken to ensure that modifying this rule does not lead to misuse of TRS or fraudulent billing to the TRS Fund? More generally, are there other precautions the Commission should take to prevent the inappropriate or excessive provision of TRS in video conferences, with the intention of increasing a TRS provider's compensable minutes?

Integrating Other Types of TRS With Video Conferencing

The Commission seeks comment generally on the need to facilitate the integration of non-VRS types of TRS with video conferencing and on the existence and progress of any efforts to develop technology to enable such integration. To the extent that such integration is needed and feasible, should the Commission adopt service-specific rule changes, *e.g.,* amendments analogous to those proposed above for VRS, to address the integration of other types of TRS with video conferencing? What rule changes would facilitate the integrated provision of each type of TRS with video conferencing, ensure the appropriate use of these TRS Fund-supported services in that context, and prevent waste, fraud, and abuse?

IP Relay. The Commission seeks comment on the extent to which the integrated provision of IP Relay in video conferences would facilitate functionally equivalent communication. Would such integrated provision of IP Relay enhance functionally equivalent communication in video conferences for those segments of the TRS-eligible population served by IP Relay, such as persons who are deafblind and persons with speech disabilities? As the Commission has noted, IP Relay can be enhanced with adaptive technologies such as refreshable Braille displays and

screen readers, making it particularly useful for consumers who are deafblind. Have methods and technologies been developed to enable such integrated provision of IP Relay? Could the needs of these communities be served more efficiently or effectively if IVCS providers make available text-to-speech and speech-to-text (captioning) functionality, pursuant to part 14 of the Commission's rules? Alternatively, would IP Relay be needed for certain populations to effectively participate in a video conversation in a way that is functionally equivalent?

If the integrated provision of IP Relay with video conferencing is achievable, what service-specific amendments to the rules would facilitate such integration, ensure the appropriate provision of IP Relay in this context, and prevent waste, fraud, and abuse? How can the Commission ensure that only registered IP Relay users can use IP Relay in a video conference? Would the same sign-on procedure and request for a CA work in the context of IP Relay as for VRS? Are there CA-related issues for IP Relay similar to those proposed above for VRS?

IP CTS. The Commission seeks comment on the extent to which the integrated provision of IP CTS in video conferences would facilitate functionally equivalent communication for IP CTS users. Have methods and technologies been developed to enable such integrated provision of IP CTS? The Commission notes that IVCS providers are permitted to meet the part 14 performance objective of providing auditory information in visual form either by implementing a captioning solution on the platform itself or by using third-party solutions available to consumers at nominal cost. *See* 47 CFR 14.20(a)(3), 14.21(b)(2)(iv). Some IVCS providers currently offer captioning. To the extent that technology is developed for integrating IP CTS with video conferencing, are IVCS providers likely to implement such technology, either to comply with part 14 or to provide an additional captioning option for users? If the integrated provision of IP CTS with video conferencing is achievable, what rule changes would ensure appropriate use of such services in that context, while preventing waste, fraud, and abuse?

Non-Internet-Based TRS. The Commission seeks comment on whether and how the Commission should amend its rules to facilitate the provision in video conferences of non-internet-based TRS—Text Telephone (TTY)-based TRS, Captioned Telephone Service (CTS), and Speech-to-Speech Relay (STS). For TTY-based TRS, a user calls a relay center and types the number to be called. The CA makes the telephone call and then relays the call between the parties by speaking what a text user types, and typing what a voice telephone user speaks. For STS, a CA (who is specially trained in understanding a variety of speech disorders) repeats what the caller says in a manner that makes the caller's words clear and understandable to the called party. CTS is similar to IP CTS, with captions being provided over the telephone network instead of the internet.

These services, offered through state TRS programs, are intended for use on an ordinary telephone line. While users of these services may be able to participate in an IVCS call over a dial-up connection (where available), it is unclear whether or how these forms of TRS could be integrated with video conferencing platforms. Further, given the availability of IP CTS and IP Relay, which provide the functionality of CTS and TTY-based TRS for users with internet access, it seems unlikely that there would be significant demand for integrated provision of these services in internet-based video conferences. The Commission seeks comment on this assumption. STS, however, has no internet-based equivalent. For STS, would enabling the CA, as well as the user, to participate in the video portion of a video conference permit more effective communication for the STS user? If so, have methods and technologies been developed to enable such integrated provision of STS? What service-specific rule changes would facilitate such provision of STS, ensure appropriate use of STS in that context, and prevent waste, fraud, and abuse?

Rules Applicable to All TRS

The Commission seeks comment on proposed rule amendments that would be applicable both to VRS and to any other form of TRS that is integrated with video conferencing.

Confidentiality. The Commission proposes to amend its TRS confidentiality rule to address the video conferencing context. Specifically, the Commission proposes to amend the rule to expressly prohibit CAs from disclosing non-relayed content that is communicated in a video conference, or maintaining records of such content beyond the duration of the video conference. It also proposes to amend the confidentiality rule to codify the current practice that the rule expressly applies to TRS providers as well as CAs, so that the rule explicitly covers TRS calls (including but not limited to video conferences) where TRS is provided via ASR or other automatic processes, without the involvement of a CA. The rule currently provides that CAs are prohibited from disclosing the content of any relayed conversation regardless of content, and from keeping records of the content of any conversation beyond the duration of a call, even if to do so would be inconsistent with state or local law. 47 CFR 64.604(a)(2)(i). Some features of video conferences are not explicitly addressed by this rule. For example, a CA may become aware of sidebar conversations between two or more video conference participants (whether in speech or sign language) that the CA concludes are not intended to be communicated to other participants. Or the CA may review chat conversations or PowerPoints and other presentation material that the CA is not asked to relay to participants. Therefore, such content would not be included in relayed conversation.

The proposed rule would protect this content from disclosure and would require TRS providers and CAs to destroy any notes or records of such content upon termination of the call. For example, if a CA keeps notes during a call of, *e.g.,* party names, specialized vocabulary, such notes must be destroyed at the end of the call. The Commission seeks comment on this proposal. Are additional amendments to the Commission's confidentiality rule necessary to protect the privacy of participants? For example, should the Commission also restrict CAs from disclosing the identities or other personal information regarding the participants in a video conference? Should any of the proposed restrictions on non-relayed content be applicable to other types of calls?

Exclusivity. Consistent with the Disability Advisory Committee's recommendation, the Commission proposes to prohibit exclusivity arrangements between TRS providers and IVCS providers. In general, an exclusivity arrangement is an express or implied agreement between a TRS provider and an IVCS provider that has the purpose or effect of preventing other providers from offering similar services to consumers. Such exclusivity arrangements may deprive consumers of the opportunity to rely on their chosen provider when using video conferencing services, contrary to the Commission's policy. Similarly, such exclusivity arrangements also may deprive conference hosts of the opportunity to select their preferred IVCS provider. What are the costs and benefits of exclusivity arrangements between TRS providers and IVCS providers? What types of arrangements should be

prohibited as *de facto* exclusivity agreements? Are there any arrangements of this kind that should be allowed, *e.g.,* because they would provide net economic benefits in this context? Should the Commission also prohibit exclusivity arrangements between TRS providers and manufacturers or suppliers of video conferencing equipment or software? Should the Commission require that all contracts between TRS providers and IVCS service providers (or suppliers of video conferencing equipment or software) be available for inspection?

TRS vs. Other Accessibility Measures. Video conferencing can function as a substitute for in-person meetings as well as teleconferences. Historically, the Commission has prohibited the use of TRS for in-person meetings. Further, many employers, educational institutions, health care providers, government agencies, and other entities currently provide ASL interpreting, captioning and other accommodations—either voluntarily or to fulfill obligations under the Americans with Disabilities Act (ADA), Public Law 101–336, or other laws—to ensure that persons with hearing and speech disabilities can fully participate in meetings, classes, and other activities. In these contexts, dedicated ASL interpreters, captioners, and others may be trained and gain experience in a specific subject matter and may have the opportunity to prepare in advance for a scheduled meeting or class. The Commission seeks comment on the extent to which such accommodations, as well as accessibility features that may be available on a video conferencing platform, may be more effective than TRS in making video conferences accessible. Would the universal availability of TRS in video conferences reduce the incentives of video conference organizers and hosts to provide more effective forms of accessibility? For example, is there a risk that the availability of integrated VRS in a video conference will dissuade organizers or hosts from voluntarily offering more effective ASL interpreting services, and if so, what steps should the Commission take to mitigate that risk? More generally, how can the Commission ensure that the use of TRS in video conferences does not detract from the effective implementation of ADA and other legal requirements?

Further, as stewards of the TRS Fund, the Commission has an obligation to prevent waste and ensure that TRS is available in the most efficient manner. When a non-TRS accessibility solution has been made available by a video conference organizer or an IVCS provider, are there steps the Commission should take to prevent unnecessary and potentially confusing provision of a redundant TRS solution? For example, if a video conference organizer employs or contracts for an ASL interpreting or captioning service, whether in fulfillment of legal obligations or voluntarily, should TRS Fund compensation be denied for the integrated provision of VRS in that video conference? How would such a restriction be effectuated as a practical matter? For instance, should the Commission require a VRS provider that offers integrated VRS to ensure that when VRS is requested for a video conference, the organizer or host is prompted to confirm whether or not ASL interpretation is being separately provided? To limit unnecessary requests for VRS, should the Commission require IVCS providers to make available a symbol that call organizers can activate in a call invitation or notice to indicate that ASL interpreters will be supplied on the call?

As a related matter, the Commission tentatively concludes that TRS providers must decline requests to reserve a TRS CA in advance of a scheduled video conference. The provision of ASL interpreting, captioning, and other assistance by prior reservation is a different kind of service, which is available from other sources, such as VRI services. The Commission has long held that the role of TRS is to be available for calls consumers choose to make, when they choose to make them, *i.e.,* to be the dial tone for a call that requires assistance for effective communication. For this reason, the Commission requires TRS providers to handle service requests in the order in which they are received, in accordance with speed-of-answer standards. As a consequence, the Commission has found that the practice of permitting TRS users to reserve in advance a time at which a CA will handle a call is inconsistent with the nature of TRS and the functional equivalency mandate. Allowing TRS CAs to be reserved in advance for certain kinds of calls, such as video conferences, would raise the risk that service to other users would be degraded. The Commission seeks comment on this tentative conclusion.

Costs and Benefits. The Commission seeks comment on the costs and benefits of each of the proposed rule amendments and other possible changes discussed above, including: authorizing the integrated provision of VRS and other types of TRS with video conferences; specifying modified methods of VRS user validation and call detail recording for video conferences; addressing the use of multiple VRS CAs, service to multiple VRS users, and call takeover in video conferences; changes to the privacy screen rule; changes to the TRS confidentiality rules; prohibiting exclusivity agreements between TRS providers and IVCS providers, equipment manufacturers, and software suppliers; and preventing disincentives for and duplication of the provision of accommodations by video conference organizers and providers.

The Commission also seeks comment on the specific costs that providers of each type of TRS (as opposed to IVCS providers and other parties) would incur to provide service in video conferences on an integrated basis. For example, the Commission seeks estimates of the research and development costs incurred by TRS providers to develop, and engineering costs to build, test, maintain, and update, those aspects of integration solutions in which a TRS provider is involved. It also seeks estimates of the costs TRS providers would incur to adapt their TRS operations (for example, by adjusting call routing protocols) to the integrated provision of TRS in video conferences, in accordance with the proposed rules. To what extent could there be offsetting cost savings? The Commission also requests that interested parties identify which costs would be appropriately identified as start-up or one-time costs, and which costs would be recurring.

How is demand for VRS and other forms of TRS likely to change as a result of integrating TRS with video conferencing? What is the projected impact of such increased use on costs and revenues for TRS providers? To what extent could increases in TRS minutes of use due to integration of TRS with video conferencing off-set increased costs to provide such service?

TRS Fund Compensation. In general, the Commission anticipates that allowable costs incurred by TRS providers to provide service that is integrated with video conferencing will be recovered pursuant to the Commission's current processes. That is, such costs will be reported annually by providers along with other allowable costs and will be recovered pursuant to compensation formulas determined in the relevant compensation proceedings for each form of TRS. However, comment is sought on any changes in cost categories that may be needed to reflect the costs of integration with IVCS platforms. Will the provision of TRS on video conferencing platforms require changes to the forms on which TRS providers annually report cost and demand to the TRS Fund administrator?

Are additional limits on allowable costs needed to protect against waste, fraud, and abuse in the TRS program?

At least one VRS provider indicates it is already able to provide VRS with one IVCS provider on an integrated basis. Absent a mandate, any additional costs incurred by VRS providers to provide such service, if significantly higher than costs reported to the TRS Fund administrator and reflected in applicable compensation formulas, would not be recoverable under the Commission's current guidelines for exogenous cost recovery. For example, one of the criteria for recovery of exogenous costs for VRS and IP CTS provides that the additional costs must result from new TRS service requirements or other causes beyond the provider's control. To encourage VRS providers to develop methods and technologies for providing VRS integrated with video conferencing, should the Commission provide a mechanism for additional cost recovery from the TRS Fund?

Amendment of the Commission's Rule on Multiple CAs

Section 64.604(c)(14) of the Commission's rules authorizes additional TRS Fund compensation for the involvement of multiple CAs in handling specified types of calls between two or more TRS users. The Commission proposes to amend this provision to state generally that compensation may be paid for the use of multiple CAs to handle TRS calls between users of different types of TRS where more than one CA is needed to handle the call. Adopted in 2014, § 64.604(c)(14) of the Commission's rules currently states that compensation is authorized for the provision of multiple CAs to handle TRS calls between two or more users of captioned telephone service—CTS or IP CTS—and for calls between a captioned telephone service user and a user of TTY-based TRS or VRS.

The Commission adopted this provision in 2014 to codify certain existing practices brought to its attention, whereby compensation was paid for the use of multiple CAs to handle certain types of calls. Subsequently, the Commission amended the definition of *telecommunications relay services* to reflect the statutory definition of that term as amended by the CVAA. The amended definition provides that TRS enable functionally equivalent communication between an individual who is deaf, hard of hearing, deaf-blind, or who has a speech disability and one or more individuals. 47 CFR 64.601(a)(43); *see also* 47 U.S.C. 225(a)(3). Before enactment of the CVAA, TRS was defined as enabling functionally equivalent communication between an individual who has a hearing impairment or speech impairment and an individual who does not have a hearing impairment or speech impairment. 47 U.S.C. 225(a)(3) (2009). In proposing the 2014 amendment, the Commission explained that the revised definition would allow compensation from the TRS Fund for relay calls involving two or more persons using different forms of relay services, including calls whose handling may require more than one CA. However, in adopting the amended definition of TRS, the Commission did not modify the multiple-CA rule to reflect its stated intent regarding compensation for calls handled by multiple CAs. As a result, some categories of calls that qualify as TRS under the amended statutory definition and that may warrant multiple CAs, are not currently addressed by the multiple-CA rule. For example, the current rule does not address when the use of two CAs is appropriate for calls between users of IP Relay and other forms of TRS.

The Commission proposes to amend the multiple-CA rule to broaden its scope, to more fully reflect the Commission's stated intent in adopting the amended definition of TRS. Under the proposed amendment, the rule would state that compensation may be paid for more than one CA to handle, among other categories, calls between users of different types of relay services where more than one CA is warranted. Comment is sought on this proposal.

Advancing Diversity, Equity, Inclusion, and Accessibility

The Commission, as part of its continuing effort to advance digital equity for all, including people of color, persons with disabilities, persons who live in rural or Tribal areas, and others who are or have been historically underserved, marginalized, or adversely affected by persistent poverty or inequality, invites comment on any equity-related considerations and benefits, if any, that may be associated with the proposals and issues discussed herein. The term *equity* is used here consistent with Executive Order 13985 as the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. Specifically, the Commission seeks comment on how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility.

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), 5 U.S.C. 603, the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this document. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadline for comments provided in this document.

Need for, and Objective of, Proposed Rules. The Commission proposes to amend its rules to improve the accessibility of IVCS, a form of ACS. First, the Commission proposes to amend part 14 of its rules, which governs accessibility of ACS. The Commission proposes to add performance objectives that specifically enable the accessibility of IVCS. The Commission proposes that such performance objectives include the provision of speech-to-text (captioning) capabilities; text-to-speech capabilities; and enabling of ASL interpreting. The Commission seeks comment on whether additional amendments are needed to ensure that video conferencing is accessible. The Commission also seeks comment on whether technical standards are available or could be fashioned for use as safe harbors.

Second, the Commission proposes to amend part 64 of its rules, governing TRS, to provide that the Interstate TRS Fund can be used to support the integrated provision of relay service in video conferences—whether or not the video conferencing platform can be accessed via a dial-up telephone call. In addition, the Commission proposes to modify its rules to facilitate such integration, ensure the appropriate use of VRS with video conferencing, and prevent waste, fraud, and abuse.

Legal Basis. The authority for this proposed rulemaking is contained in sections 1, 2, 3, (4)(i), (4)(j), 225, and 716 of the Act, 47 U.S.C. 151, 152, 153, 154(i), 154(j), 225, 617.

Small Entities Impacted. The proposed rules will affect the

obligations of providers of IVCS and providers of TRS. These services can be included within the broad economic category of All Other Telecommunications.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements. The proposed changes for which comment is sought in this document, if adopted, would impose new or modified reporting, recordkeeping or other compliance obligations on certain small entities that provide IVCS or TRS.

The Commission's existing rules require that each manufacturer of equipment (including software) used to provide ACS and each provider of such services not otherwise exempt maintain, in the ordinary course of business and for a reasonable period, records documenting the efforts taken by such manufacturer or service provider to implement sections 255 and 716 of the Act, including: information about the manufacturer's or provider's efforts to consult with individuals with disabilities; descriptions of the accessibility features of its products and services; and information about the compatibility of such products and services with peripheral devices or specialized customer premise equipment commonly used by individuals with disabilities to achieve access.

The Commission's existing rules require that an officer of each manufacturer of equipment (including software) used to provide ACS and an officer of each provider of such services submit to the Commission an annual certificate that records are being kept in accordance with the above recordkeeping requirements, unless such manufacturer or provider has been exempted from compliance with section 716 under applicable rules.

Because of the diverse manufacturers of equipment used to provide ACS and diverse providers of ACS that may be subject to section 716 of the Act, the multiple general and entity-specific factors used in determining, whether for a given manufacturer (or service provider) accessibility for a particular item of ACS equipment (or a particular service) is achievable, and the various provisions of section 716 of the Act and the proposed rules on when and to what extent accessibility must be incorporated into a given item of ACS equipment or service, it is difficult to estimate the costs of compliance for those small entities that may not be covered by a waiver, should the Commission choose to apply any such waivers. Accordingly, the Commission seeks comment on the costs of compliance with these proposed rules.

The proposed amendments to the Commission's rules governing TRS are designed to facilitate the use of TRS CAs in video conferences, ensure the appropriate use of TRS with video conferencing, and prevent waste, fraud, and abuse. These modifications would only apply to the extent that users of a specific small entity TRS provider participate in video conference calls. Otherwise, the TRS compliance requirements would remain unchanged.

Steps Taken to Minimize Significant Impact on Small Entities, and Significant Alternatives Considered. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; the use of performance rather than design standards; and an exemption from coverage of the rule, or any part thereof, for such small entities.

The Commission seeks comment from all interested parties. Small entities are encouraged to bring to the Commission's attention any specific concerns they may have with the proposals outlined in this document. The Commission expects to consider the economic impact on small entities, as identified in comments filed, in reaching its final conclusions and taking action in this proceeding.

Federal Rules Which Duplicate, Overlap, or Conflict With, the Commission's Proposals. None.

Initial Paperwork Reduction Act of 1995 Analysis

This document may contain new or modified information collection(s) subject to the Paperwork Reduction Act of 1995, Public Law 104–13 (PRA). If the Commission adopts any new or modified information collection requirements, they will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA, 44 U.S.C. 3507(d). OMB, the general public, and other federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees. 44 U.S.C. 3506(c)(4).

List of Subjects

47 CFR Part 14

Communications, Individuals with disabilities, Reporting and recordkeeping requirements.

47 CFR Part 64

Individuals with disabilities, Reporting and recordkeeping requirements, Telecommunications, Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 14 and 64 as follows:

PART 14—ACCESS TO ADVANCED COMMUNICATIONS SERVICES AND EQUIPMENT BY PEOPLE WITH DISABILITIES

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

Authority: 47 U.S.C. 151–154, 255, 303, 403, 503, 617, 618, 619 unless otherwise noted.

■ 2. Amend § 14.21 by revising paragraphs (b)(1)(ix) and (b)(2)(iv) and adding paragraph (b)(4) to read as follows:

§ 14.21 Performance Objectives.

* * * * *

(b) * * *

(1) * * *

(ix) *Operable without speech.* Provide at least one mode that does not require user speech. For interoperable video conferencing services, provide at least text-to-speech capability.

* * * * *

(2) * * *

(iv) *Availability of auditory information.* Provide auditory information through at least one mode in visual form and, where appropriate, in tactile form. For interoperable video conferencing services, provide at least one mode with captions that are accurate and synchronous. The accuracy and latency of such captions should be comparable to that provided on TRS Fund-supported captioned telephone services.

* * * * *

(4) *Interoperable Video Conferencing Service.*

(i) *Sign language interpretation.* Interoperable video conferencing

services shall enable the use of sign language interpretation, including the transmission of user requests for sign language interpretation to providers of video relay service and other entities and the provision of sufficient video quality to support sign language communication.

(ii) *User interface.* Interoperable video conferencing services shall provide user interface control functions that permit users to adjust the display of captions, speakers and signers, and other features for which user interface control is necessary for accessibility.

* * * * *

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 3. The authority citation for part 64 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 154, 201, 202, 217, 218, 220, 222, 225, 226, 227, 227b, 228, 251(a), 251(e), 254(k), 255, 262, 276, 403(b)(2)(B), (c), 616, 617, 620, 1401–1473, unless otherwise noted; Pub. L. 115–141, Div. P, sec. 503, 132 Stat. 348, 1091.

■ 4. The authority citation for subpart F continues to read as follows:

Authority: 47 U.S.C. 151–154; 225, 255, 303(r), 616, and 620.

■ 5. Amend § 64.601 by:

■ a. Redesignating paragraphs (a)(21) through (24) as paragraphs (a)(22) through (25), and adding new paragraph (a)(21);

■ b. Redesignating paragraphs (a)(25) and (26) as paragraphs (a)(27) and (28), and adding new paragraph (a)(26);

■ c. Redesignating paragraphs (a)(27) through (50) as paragraphs (a)(30) through (53), and adding new paragraph (29); and

■ d. Redesignating paragraphs (a)(51) through (55) as paragraphs (a)(55) through (59), and adding new paragraph (a)(54).

The additions read as follows:

§ 64.601 Definitions and provisions of general applicability.

(a) * * *

(21) *Integrated VRS.* The provision of VRS in a video conference whereby the CA is included as a participant in the video conference and communication between the CA and the participants takes place on the video conferencing platform rather than through a separate connection.

* * * * *

(26) *Interoperable video conference service (IVCS).* Has the meaning defined in part 14 of this chapter.

* * * * *

(29) *Multi-party video conference.* A video conference call with three or more participants, excluding VRS CAs and any other participant providing an accommodation for a participant.

* * * * *

(54) *Video conference.* A session of IVCS involving two-way real-time communication between two or more IVCS users.

* * * * *

■ 6. Amend § 64.604 by:

■ a. Revising paragraphs (a)(2)(i) and (a)(6);

■ b. Adding paragraph (c)(5)(iii)(D)(*2*)(*xi*);

■ c. Revising paragraphs (c)(5)(iii)(E)(*2*) and (c)(14);

■ d. Adding paragraph (c)(15); and

■ e. Revising paragraph (d).

The revisions and additions read as follows:

§ 64.604 Mandatory minimum standards.

* * * * *

(a) * * *

(2) * * *

(i) Except as authorized by section 705 of the Communications Act, 47 U.S.C. 605, TRS providers and CAs are prohibited from disclosing the content of any relayed conversation (and any non-relayed content communicated in a video conference) regardless of content, and with a limited exception for STS CAs, from keeping records of the content of any conversation (and any non-relayed content communicated in a video conference) beyond the duration of a call, even if to do so would be inconsistent with state or local law. STS CAs may retain information from a particular call in order to facilitate the completion of consecutive calls, at the request of the user. The caller may request the STS CA to retain such information, or the CA may ask the caller if he wants the CA to repeat the same information during subsequent calls. The CA may retain the information only for as long as it takes to complete the subsequent calls.

* * * * *

(6) *Visual privacy screens/idle calls.*

(i) Except as provided in paragraph (a)(6)(ii)(A) of this section, a VRS CA may not enable a visual privacy screen or similar feature during a VRS call. Except as provided in paragraph (a)(6)(ii)(B) of this section, a VRS CA must disconnect a VRS call if the caller or the called party to a VRS call enables a privacy screen or similar feature for more than five minutes or is otherwise unresponsive or unengaged for more than five minutes, unless the call is a 9–1–1 emergency call or the caller or called party is legitimately placed on hold and is present and waiting for active communications to commence. Prior to disconnecting the call, the CA must announce to both parties the intent to terminate the call and may reverse the decision to disconnect if one of the parties indicates continued engagement with the call.

(ii) A VRS CA providing integrated VRS in a multi-party video conference:

(A) May temporarily turn off the CA's video camera when engaged in team interpreting, if the other CA is actively providing ASL interpretation;

(B) May stay connected to the video conference if the VRS user who requested service has turned off the user's camera, as long as that user stays connected to the video conference; and

(C) If five minutes elapse in which no party is responsive or engaged in conversation, the CA shall announce that VRS will be terminated and shall disconnect from the video conference.

* * * * *

(c) * * *

(5) * * *

(iii) * * *

(D) * * *

(*2*) * * *

(*xi*) For the provision of integrated VRS in a video conference, in lieu of the information specified in paragraphs (v) and (vi) of this section, a VRS provider may submit information, in accordance with instructions issued by the administrator, that sufficiently identifies the VRS user requesting service and the video conference in which service was provided.

* * * * *

(E) * * *

(*2*) TRS minutes of use for purposes of cost recovery from the TRS Fund are defined as the minutes of use for completed interstate or internet-based TRS calls placed through the TRS center beginning after call set-up and concluding after the last message call unit. For video conferences, a VRS provider's TRS minutes of use begin when a VRS CA is connected to a video conference and two or more participants are actively present, and ends when the CA disconnects from the video conference or when fewer than two participants are actively present, whichever is earlier.

* * * * *

(14) *TRS calls requiring the use of multiple CAs.* TRS Fund compensation may be paid for more than one CA to handle the following types of calls:

(i) VCO-to-VCO calls between multiple captioned telephone relay service users, multiple IP CTS users, or captioned telephone relay service users and IP CTS users;

(ii) Calls between users of different types of relay services for which more than one CA is warranted; and

(iii) Video conferences where more than one CA is warranted.

(15) *Exclusivity Agreements.* A TRS provider may not enter into an agreement or any other arrangement with an IVCS provider if such agreement or arrangement would give the TRS provider exclusive access among TRS providers to the IVCS provider's facilities or such agreement or arrangement would give the IVCS provider exclusive access among IVCS providers to the TRS provider's service via a video connection.

(d) The applicable requirements of § 9.14 of this chapter and §§ 64.611, 64.615, 64.621, 64.631, 64.632, 64.644, 64.5105, 64.5107, 64.5108, 64.5109, and 64.5110 are to be considered mandatory minimum standards.

■ 7. Amend § 64.615 by revising paragraph (a)(1)(i) to read as follows:

§ 64.615 TRS User Registration Database and administrator.

(a) * * *

(1) * * *

(i) Validation shall occur during the call setup process, prior to the placement of the call, except that validation of the provision of integrated VRS in a video conference shall occur prior to the connection of a VRS CA to the video conference.

* * * * *

■ 8. Add § 64.644 to subpart F to read as follows:

§ 64.644 Provision of Integrated VRS in Video Conferences.

(a) A VRS provider may provide integrated VRS in a video conference upon request by a registered VRS user (or by a person authorized by a registered enterprise VRS user).

(b) A VRS provider providing integrated VRS in a video conference shall:

(i) Collect from the party requesting service sufficient information to confirm the requesting party's registration for VRS pursuant to the applicable requirements of §§ 64.611 and 64.615; and

(ii) Terminate the CA's connection to the video conference no later than when the requesting VRS user disconnects from the video conference.

(c) A VRS provider may assign more than one CA to participate in a multi-party video conference.

[FR Doc. 2023–16672 Filed 8–4–23; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 12, 22, 47, and 52

[FAR Case 2019–017; Docket No. FAR–2019–0017, Sequence No. 1]

RIN 9000–AO00

Federal Acquisition Regulation: Training To Prevent Human Trafficking for Certain Air Carriers

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a section of the Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act of 2018, which requires that domestic carriers who contract with the Federal Government to provide air transportation must submit an annual report with certain information related to prevention of human trafficking.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before October 6, 2023 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2019–017 to the Federal eRulemaking portal at *http://www.regulations.gov* by searching for ''FAR Case 2019–017''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2019–017''. Follow the instructions provided on the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2019–017'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite ''FAR Case 2019–017'' in all correspondence related to this case. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. Public comments may be submitted as an individual, as an organization, or anonymously (see frequently asked questions at *https://www.regulations.gov/faq*). To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Malissa Jones, Procurement Analyst, at 571–882–4687, or by email at *malissa.jones@gsa.gov.* For information pertaining to status, publication schedules, or alternate instructions for submitting comments if *https://www.regulations.gov* cannot be used, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAR Case 2019–017.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to amend the FAR to implement section 111 of the Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act of 2018 (Pub. L. 115–425), enacted January 8, 2019. Section 111 amends 49 U.S.C. 40118 to require that domestic carriers who contract with the Federal Government to provide air transportation must submit an annual report to the Administrator of General Services, the Secretary of Transportation, the Secretary of Labor, the Administrator of the Transportation Security Administration, and the Commissioner of U.S. Customs and Border Protection. The FAR will require the following information in the report:

- The number of personnel trained in the detection and reporting of potential human trafficking (as described in 22 U.S.C. 7102 in the paragraphs titled ''Severe forms of trafficking in persons'' and ''Sex trafficking''), including the training required under 49 U.S.C. 44734(a)(4);
- The number of notifications of potential human trafficking victims received from contractor personnel, subcontractors, or passengers; and
- Whether the contractor notified the Global Human Trafficking Hotline, another comparable hotline, or law enforcement at the relevant airport of the potential human trafficking victim for each such notification of potential human trafficking, and if the contractor made a notification, the date the notification was made and the method of notification (*e.g.,* text to Hotline, call to law enforcement).

Section 111 does not apply to contracts awarded by the Department of Defense.

II. Discussion and Analysis

The proposed rule reflects the new reporting requirements conveyed in section 111 and updates the statutory citations for 49 U.S.C. 40118, Government-financed air transportation, throughout the FAR, removing obsolete references to section 5 of the International Air Transportation Fair Competitive Practices Act of 1974.

A summary of the proposed changes follows.

A. FAR Parts 12, 22, and 47

In 12.503(b)(4), 47.101, and 47.402, references to Government-financed air transportation are revised to clarify the statutory title of 49 U.S.C. 40118. References to the Fly America Act are maintained to avoid confusion throughout the contracting workforce.

In 22.1703, Policy, a cross-reference to 47.405(b) is added to point to the prescription for a new contract clause that includes reporting requirements concerning training to prevent human trafficking for domestic carrier air transportation.

New section 47.400, Scope of Subpart, is added to introduce the statute implemented in the section, for consistency with the standard structure of the FAR.

The definition of ''U.S.-flag air carrier'' in FAR 47.401 is revised to reflect the terminology used in 49 U.S.C. 41102, and referenced in 49 U.S.C. 40118. Conforming changes are made to the definition of ''U.S.-flag air carrier'' in FAR clause 52.247–63, Preference for U.S.-Flag Air Carriers.

FAR 47.405 is amended to include a prescription for the new clause at FAR 52.247–XX, Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking. The new clause will be required for solicitations and contracts, including those below the simplified acquisition threshold (SAT) and those for commercial services, that are with a U.S.-flag carrier for the transportation by air of passengers. As a result, a conforming change in the reference to 47.405 is made at 12.503, Applicability of certain laws to Executive agency contracts for the acquisition of commercial products and commercial services.

B. FAR Part 52

New FAR clause 52.247–XX, Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking, contains the reporting requirements described in section 111 and provides instructions to contractors on when and how to submit the annual report, in addition to clarifications on the type of ''personnel'' for whom training data is to be included in the report. It applies to acquisitions below the SAT and to commercial services (see section III of this preamble). As a result, the clause is added to 52.212–5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Products and Commercial Services and 52.213–4, Terms and Conditions—Simplified Acquisitions (Other than Commercial Products and Commercial Services).

FAR clause 52.247–63, Preference for U.S. Flag Air Carriers, is amended to revise the definition of ''U.S.-flag air carrier'' as described in section II.A. of this preamble. In addition, obsolete references to requirements in Section 5 of the International Air Transportation Fair Competitive Practices Act of 1974 are replaced with current requirements in 49 U.S.C. 40118, Government-financed air transportation.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Products (Including Commercially Available Off-The-Shelf (COTS) Items), or for Commercial Services

This rule proposes a new clause at FAR 52.247–XX, Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking, to implement the requirements of section 111 of the Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act of 2018 (Pub. L. 115–425). The clause is prescribed at FAR 47.405(b) for use in solicitations and contracts with a U.S.-flag air carrier for the transportation by air of passengers. This clause is not applicable to solicitations issued or contracts awarded by the Department of Defense. The Federal Acquisition Regulatory Council (FAR Council) plans at the final rule stage to make the following determinations with respect to the rule's application to contracts at or below the simplified acquisition threshold (SAT) and for the acquisition of commercial services, but not commercial products or COTS items. Discussion of these determinations is set forth below.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

41 U.S.C. 1905 governs the applicability of laws to acquisitions at or below the SAT. Section 1905 generally limits the applicability of new laws when agencies are making acquisitions at or below the SAT, but provides that such acquisitions will not be exempt from a provision of law under certain circumstances, including when the FAR Council makes a written determination and finding that it would not be in the best interest of the Federal Government to exempt contracts and subcontracts in amounts not greater than the SAT from the provision of law. The FAR Council intends to make a determination to apply this statute to acquisitions at or below the SAT.

B. Applicability to Contracts for the Acquisition of Commercial Products and Commercial Services, Including Commercially Available Off-The-Shelf (COTS) Items

41 U.S.C. 1906 governs the applicability of laws to contracts for the acquisition of commercial products and commercial services, and is intended to limit the applicability of laws to contracts for the acquisition of commercial products and commercial services. Section 1906 provides that if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt commercial contracts, the provision of law will apply to contracts for the acquisition of commercial products and commercial services.

41 U.S.C. 1907 states that acquisitions of COTS items will be exempt from certain provisions of law unless the Administrator for Federal Procurement Policy makes a written determination and finds that it would not be in the best interest of the Federal Government to exempt contracts for the procurement of COTS items.

The FAR Council intends to make a determination to apply this statute to acquisitions for commercial services. Considering that air transportation, such as passenger air travel, is a commercial service, there is no need to apply section 111 to the acquisition of commercial products.

Considering that air transportation does not meet the definition of a COTS item (*i.e.,* it is a service, not a product), section 111 cannot apply to acquisitions of such items regardless of the requirements at 41 U.S.C. 1907. Therefore, the Administrator for Federal Procurement Policy does not intend to make a determination to apply this statute to acquisitions for COTS items.

C. Determinations

Section 111 of the Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act of 2018, 49 U.S.C. 40118(g), requires that domestic carriers who contract with the Federal Government to provide air transportation provide an annual report to the Administrator of General

Services, the Secretary of Transportation, the Secretary of Labor, the Administrator of the Transportation Security Administration, and the Commissioner of U.S. Customs and Border Protection, with the following information:

- The number of personnel trained in the detection and reporting of potential human trafficking (as described in 22 U.S.C. 7102 in the paragraphs titled ''Severe forms of trafficking in persons'' and ''Sex trafficking''), including the training required under 49 U.S.C. 44734(a)(4);
- The number of notifications of potential human trafficking victims received from contractor personnel, subcontractors, or passengers; and
- Whether the contractor notified the Global Human Trafficking Hotline, another comparable hotline, or law enforcement at the relevant airport of the potential human trafficking victim for each such notification of potential human trafficking, and if the contractor made a notification, the date the notification was made and the method of notification (*e.g.,* text to Hotline, call to law enforcement).

The purpose of the Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act of 2018 is to combat human trafficking. Section 111 of the Act is meant to further that objective. The purpose of this rule is to implement section 111.

The law is silent on the applicability of these requirements to acquisitions at or below the SAT and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1905 and its application to acquisitions at or below the SAT. Therefore, it does not apply to acquisitions at or below the SAT unless the FAR Council makes a written determination as provided at 41 U.S.C. 1905.

Application of the law to contracts at or below the SAT will further the important public policy objective of prohibiting the trafficking of persons. According to the Federal Procurement Data System, approximately seventy percent (70%) of the contracts for air transportation (as identified either by the Product Service Codes of V111 (Air Freight), V121 (Air Charter), V211 (Air Passenger), and V221 (Passenger air charter) or by North American Industry Classification System codes in the 4811XX and 4822XX fields (Scheduled Air Transportation and Nonscheduled Air Transportation industries)) were at or below the SAT during fiscal years 2021 and 2022. Failure to apply section 111 to contracts at or below the SAT would exclude a significant number of acquisitions, which would undermine the important public policy objective of prohibiting human trafficking.

For this reason, it is in the best interest of the Federal Government to apply the requirements of the rule to contracts at or below the SAT.

The law is silent on the applicability of these requirements to acquisitions of commercial products and commercial services and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1906 and its application to acquisitions of commercial products and commercial services. Therefore, it does not apply to acquisitions of commercial products and commercial services unless the FAR Council makes a written determination as provided at 41 U.S.C. 1906.

Considering that air transportation, such as passenger air travel, is a commercial service, failing to apply section 111 to the acquisition of commercial services would essentially be failing to implement section 111 in its entirety. For this reason, it is in the best interest of the Federal Government to apply the requirements of the rule to contracts for commercial services.

The law is silent on the applicability of this requirement to acquisitions of COTS items and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1907 and its application to acquisitions of COTS items. Therefore, it does not apply to acquisitions of COTS items unless the Administrator for Federal Procurement Policy makes a written determination as provided at 41 U.S.C. 1907.

However, considering that air transportation does not meet the definition of a COTS item (*i.e.,* it is a service, not a product), section 111 cannot apply to acquisitions of such items regardless of the requirements at 41 U.S.C. 1907. Therefore, no determination needs to be made regarding the application to acquisitions of COTS items.

IV. Expected Impact of the Rule

This proposed rule contains a reporting requirement for domestic carriers who contract with the Federal Government (except for DoD) for air transportation of passengers to provide an annual report to five agencies on the number of personnel trained in the detection of human trafficking, the number of notifications of human trafficking the contractor received, and actions the contractor took with regards to those notifications.

This proposed rule is not creating a training requirement nor does this contract clause create a mandatory reporting requirement to hot lines and law enforcement; the training requirement already existed prior to section 111 (*e.g.,* 49 U.S.C. 44734(a)(4)) and applies to all U.S.-flag air carriers, regardless of whether they are contractors of the Federal Government. This proposed rule simply requires data related to the training that has occurred and notifications that have been made.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

VI. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612, because this rule will impact domestic air carriers (*i.e.,* U.S.-flag air carriers as described in 49 U.S.C. 41102), including small business domestic air carrier. The estimated number of total small entities to which this rule could apply is 196 though it is likely much lower since it is unknown how many are considered U.S.-flag air carriers in accordance with 49 U.S.C. 41102 and actually impacted by this rule. However, an Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

DoD, GSA and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement section 111 of the Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act of 2018 (Pub. L. 115–425). Promulgation of the FAR is authorized by 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113. The legal basis for the proposed rule is section 111 of Public Law 115–425.

Section 111 requires that domestic carriers who contract with the Federal Government to provide transportation by air of passengers must submit an annual report to the Administrator of GSA, the Secretary of

Transportation, the Secretary of Labor, the Administrator of the Transportation Security Administration, and the Commissioner of U.S. Customs and Border Protection. The FAR will require the following information in the report:

- The number of personnel trained in the detection and reporting of potential human trafficking (as described in 22 U.S.C. 7102 in the paragraphs titled ''Severe forms of trafficking in persons'' and ''Sex trafficking''), including the training required under 49 U.S.C. 44734(a)(4);
- The number of notifications of potential human trafficking victims received from contractor personnel, subcontractors, or passengers; and
- Whether the contractor notified the Global Human Trafficking Hotline, another comparable hotline, or law enforcement at the relevant airport of the potential human trafficking victim for each such notification of potential human trafficking; and if the contractor made a notification, the date the notification was made and the method of notification (*e.g.,* text to Hotline, call to law enforcement).

Section 111 does not apply to contracts awarded by the Department of Defense.

The proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule will impact domestic air carriers (*i.e.,* U.S.-flag air carriers as described in 49 U.S.C. 41102), including small business U.S.-flag air carriers.

In the Small Business Administration's Dynamic Small Business Search (DSBS) database on April 19, 2023, there were 87 small businesses registered under the North American Industry Classification System (NAICS) codes for ''air transportation.'' It is unknown how many of these 87 small businesses are considered U.S.-flag air carriers in accordance with 49 U.S.C. 41102. According to the Federal Procurement Data System (FPDS), in fiscal year 2022, civilian agencies awarded contracts under NAICS codes in the 4811XX and 4822XX fields (Scheduled Air Transportation and Nonscheduled Air Transportation industries) to 196 unique small businesses. It is unknown how many of these 196 small businesses are considered U.S.-flag air carriers in accordance with 49 U.S.C. 41102. Therefore, the estimated number of total small entities to which this rule could apply is 196 though it is likely much lower since it is unknown how many are considered U.S.-flag air carriers in accordance with 49 U.S.C. 41102 and actually impacted by this rule.

This proposed rule does not include any recordkeeping or other compliance requirements for small businesses. However, the proposed rule does contain a reporting requirement for small businesses. Small business U.S.-flag air carriers who contract with the Federal Government (except for DoD) for air transportation will be required to provide an annual report to five agencies, on the number of personnel trained in the detection of human trafficking, the number of notifications of human trafficking the contractor received, and actions the contractor took with regards to those notifications.

This proposed rule is not creating a training requirement nor does this contract clause create a mandatory reporting requirement to hot lines and law enforcement; those requirements already existed prior to section 111 (*e.g.,* 49 U.S.C. 44734(a)(4)), and are applied to all U.S.-flag air carriers, regardless of whether they are contractors of the Federal Government. This proposed rule simply requires data related to the training that has occurred and notifications that have been made.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known significant alternative approaches that would accomplish the stated objectives.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the SBA. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit comments separately and should cite 5 U.S.C. 610 (FAR case 2019–017), in correspondence.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501–3521) applies because the proposed rule contains information collection requirements. Accordingly, the Regulatory Secretariat Division has submitted a request for approval of a new information collection requirement concerning FAR case 2019–017, Training to Prevent Human Trafficking for Certain Air Carriers, to the Office of Management and Budget. The burden associated with this information collection will be added to OMB Control No. 9000–0061, FAR Part 47 Transportation Requirements, when FAR case 2019–017 is finalized.

A. Estimated Public Reporting Burden

Public reporting burden for this collection of information is estimated to average 5 hours per response, which includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The annual reporting burden is estimated as follows:

Respondents: 180.
Responses per respondent: 1.
Total annual responses: 180.
Preparation hours per response: 5.
Total response burden hours: 900.

B. Request for Comments Regarding Paperwork Burden

Submit comments on this collection of information no later than October 6, 2023 through *https://www.regulations.gov* and follow the instructions on the site. All items submitted must cite OMB Control No. 9000–0061. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

Public comments are particularly invited on:

- The necessity of this collection of information for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility;
- The accuracy of the estimate of the burden of this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Requesters may obtain a copy of the supporting statement from the General Services Administration, Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control Number 9000–0061 in all correspondence.

List of Subjects in 48 CFR Parts 1, 12, 22, 47, and 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA propose amending 48 CFR parts 1, 12, 22, 47, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 12, 22, 47, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

■ 2. In section 1.106, amend the table by adding an entry for ''52.247–XX'' to read as follows:

1.106 OMB approval under the Paperwork Reduction Act.

* * * * *

FAR segment	OMB control No.
* * * * *	
52.247–XX	9000–0061
* * * * *	

PART 12—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 3. Amend section 12.503 by revising paragraph (b)(4) to read as follows:

12.503 Applicability of certain laws to Executive agency contracts for the acquisition of commercial products and commercial services.

* * * * *

(b) * * *

(4) 49 U.S.C. 40118, Requirement for a clause under a provision of the Government-financed air transportation statute, commonly referred to as the Fly America Act (see 47.405(a)).

* * * * *

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

■ 4. Amend section 22.1703 by revising the introductory text to read as follows:

22.1703 Policy.

The United States Government has adopted a policy prohibiting trafficking in persons, including the trafficking-related activities below. Additional information about trafficking in persons may be found at the website for the Department of State's Office to Monitor and Combat Trafficking in Persons at *http://www.state.gov/j/tip/.* See 47.405(b) for contract reporting requirements concerning training to prevent human trafficking for domestic carrier air transportation; 47.405(b) is not applicable to contracts awarded by the Department of Defense. Government solicitations and contracts shall—

* * * * *

PART 47—TRANSPORTATION

■ 5. Amend section 47.101 by revising paragraph (g) to read as follows:

47.101 Policies.

* * * * *

(g) Agencies shall comply with the requirements for Government-financed air transportation (commonly referred to as the Fly America Act), the Cargo Preference Act, and related statutes as prescribed in subparts 47.4, Air Transportation by U.S.-Flag Carriers, and 47.5, Ocean Transportation by U.S.-Flag Vessels.

* * * * *

■ 6. Add section 47.400 to subpart 47.4 to read as follows:

Subpart 47.4—Air Transportation by U.S.-Flag Carriers

47.400 Scope of subpart.

This subpart prescribes policies and procedures for implementing 49 U.S.C. 40118, Government-financed air transportation, commonly referred to as the Fly America Act.

* * * * *

■ 7. Amend section 47.401 by revising the definition of ''U.S.-flag air carrier'' to read as follows:

47.401 Definitions.

* * * * *

U.S.-flag air carrier means an entity granted authority to provide air transportation in the form of a certificate of public convenience and necessity under 49 U.S.C. 41102.

■ 8. Revise section 47.402 to read as follows:

47.402 Policy.

Federal employees and their dependents, consultants, contractors, grantees, and others must use U.S.-flag air carriers for U.S. Government-financed international air travel and transportation of their personal effects or property, if available (49 U.S.C. 40118, Government-financed air transportation, commonly referred to as the Fly America Act).

■ 9. Revise section 47.405 to read as follows:

47.405 Contract clauses.

(a) The contracting officer shall insert the clause at 52.247–63, Preference for U.S.-Flag Air Carriers, in solicitations and contracts whenever it is possible that U.S. Government-financed international air transportation of personnel (and their personal effects) or property will occur in the performance of the contract. This clause does not apply to contracts awarded using the simplified acquisition procedures in part 13 or contracts for commercial products (see part 12).

(b) The contracting officer shall insert the clause at 52.247–XX, Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking, in solicitations and contracts with a U.S.-flag air carrier for the transportation by air of passengers. This clause is not applicable to solicitations issued or contracts awarded by the Department of Defense.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 10. Amend section 52.212–5 by revising the date of the clause and adding paragraph (c)(10) to read as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services (DATE)

* * * * *

(c) * * *

__ 10) 52.247–XX, Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking (DATE) (49 U.S.C. 40118(g)).

* * * * *

■ 11. Amend section 52.213–4 by revising the date of the clause; and adding paragraph (b)(1)(xxii) to read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services) (DATE)

* * * * *

(b) * * *

(1) * * *

(xxii) 52.247–XX, Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking (DATE) (49 U.S.C. 40118(g)). (Applies to contracts with a U.S.-flag carrier for the transportation by air of passengers; does not apply to contracts awarded by the Department of Defense).

* * * * *

■ 12. Amend section 52.247–63 by—

■ a. Removing from the introductory text ''47.405'' and adding ''47.405(a)'' in its place;

■ b. Revising the date of the clause;

■ c. In paragraph (a), revising the definition of ''U.S.-flag air carrier''; and

■ d. Revising paragraphs (b) and (e).

The revisions read as follows:

52.247–63 Preference for U.S.-Flag Air Carriers.

* * * * *

Preference for U.S.-Flag Air Carriers (DATE)

(a) * * *

U.S.-flag air carrier means an entity granted authority to provide air transportation in the form of a certificate of public convenience and necessity under 49 U.S.C. 41102.

(b) 49 U.S.C. 40118, Government-financed air transportation (commonly referred to as the Fly America Act), requires that all Federal agencies and Government contractors and subcontractors use U.S.-flag air carriers for U.S. Government-financed international air transportation of personnel (and their personal effects) or property, to the extent that service by those carriers is available. It requires the General Services Administration to issue regulations that, in the absence of satisfactory proof of the necessity for foreign-flag air transportation, disallow expenditures from funds, appropriated or otherwise established for the account of the United States, for international air transportation secured aboard a foreign-flag air carrier if a U.S.-flag air carrier is available to provide such services.

* * * * *

(e) *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (e), in each subcontract or purchase under this contract that may involve international air transportation.

* * * * *

■ 13. Add section 52.247–XX to read as follows:

52.247–XX Reporting Requirement for U.S.-Flag Air Carriers Regarding Training to Prevent Human Trafficking.

As prescribed in 47.405(b), insert the following clause:

Reporting Requirement for U.S.-Flag Air Carriers Regarding Training To Prevent Human Trafficking (DATE)

(a) *Definitions.* As used in this clause—

Potential human trafficking has the meaning as described in paragraphs ''Severe forms of trafficking in persons'' and ''Sex trafficking'' at 22 U.S.C. 7102.

(b) *Annual reporting requirement.*

(1) In accordance with 49 U.S.C. 40118(g), the Contractor shall provide an annual report, by October 30th, via email, to the following agencies:

(i) General Services Administration: __;

(ii) U.S. Department of Transportation: *trafficking@dot.gov;*

(iii) Department of Labor: __;

(iv) Transportation Security Administration: *ics-cchtfams@tsa.dhs.gov;*

(v) U.S. Customs and Border Protection: *CLP@cbp.dhs.gov;* and

(vi) DHS Center for Countering Human Trafficking: *Info@CCHT.dhs.gov.*

(2) The report shall contain—

(i) The number of people trained in the detection and reporting of potential human trafficking, including the training required under 49 U.S.C. 44734(a)(4);

(ii) The number of notifications of potential human trafficking victims received from Contractor personnel, subcontractors, or passengers; and

(iii)(A) Whether the Contractor notified the Global Human Trafficking Hotline, another comparable hotline, or law enforcement at the relevant airport of the potential human trafficking victim for each such notification of potential human trafficking; and

(B) If the Contractor made a notification, the date the notification was made and the method of notification (*e.g.,* text to Hotline, call to law enforcement).

(c) *Training.* In accordance with 49 U.S.C. 44734 and 44738, personnel trained in the detection and reporting of potential human trafficking should include the following:

(1) Flight attendants;

(2) Ticket counter agents;

(3) Gate agents; and

(4) Other air carrier workers whose jobs require regular interaction with passengers.

(End of clause)

[FR Doc. 2023–16385 Filed 8–4–23; 8:45 am]

BILLING CODE 6820–EP–P

Notices

Federal Register
Vol. 88, No. 150
Monday, August 7, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FGIS–23–0036]

Grain Inspection Advisory Committee Meeting

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, this constitutes notice of the upcoming meeting of the Grain Inspection Advisory Committee (Advisory Committee). The Advisory Committee meets no less than once annually to advise the Secretary on the programs and services delivered by the Agricultural Marketing Service (AMS) under the U.S. Grain Standards Act. Recommendations by the Advisory Committee help AMS meet the needs of its customers, who operate in a dynamic and changing marketplace.

DATES: August 30, 2023, 8:30 a.m. to 5:00 p.m. Central & August 31, 2023, 8:30 a.m. to 12:00 p.m. Central.

Written Comments: Written public comments will be accepted on or before 11:59 p.m. ET on August 25, 2023, via email to *Kendra.C.Kline@usda.gov.* Comments submitted after this date will be provided to AMS, but the Committee may not have adequate time to consider those comments prior to the meeting.

Oral Comments: The Committee is providing the public an opportunity to present oral comments and will accommodate as many individuals and organizations as time permits. Persons or organizations wishing to make oral comments must pre-register by 11:59 p.m. ET, August 25, 2023, and may only register for one speaking slot. Instructions for registering and participating in the meeting can be obtained by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section by or before the deadline.

ADDRESSES: *Meeting Location:* The Advisory Committee meeting will take place at the AMS National Grain Center, 10383 N Ambassador Drive, Kansas City, Missouri 64153. The meeting will also be virtually accessible. Meeting information can be found at: *https://www.ams.usda.gov/about-ams/facas-advisory-councils/giac.*

FOR FURTHER INFORMATION CONTACT: Kendra Kline by phone at (202) 690–2410 or by email at *Kendra.C.Kline@usda.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the Advisory Committee is to provide advice to AMS with respect to the implementation of the U.S. Grain Standards Act (7 U.S.C. 71–87k). Information about the Advisory Committee is available on the AMS website at *https://www.ams.usda.gov/about-ams/facas-advisory-councils/giac.*

The agenda for the upcoming meeting will include general program updates, and discussions about FGIS User Fees & Budget, Vessel Fumigation Policy, Lab Scales, and Data Standards.

Public participation will be limited to written statements and interested parties who have registered to present comments orally to the Advisory Committee.

USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication of program information or related accommodations should contact Kendra Kline at the telephone number or email listed above.

Dated: August 1, 2023.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2023–16736 Filed 8–4–23; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 6, 2023 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Power of Attorney.

OMB Control Number: 0560–0190.

Summary of Collection: The form of FSA–211, Power of Attorney, is used to appoint someone to act on behalf of another as attorney-in-fact. The form gives another person legal authority to act on his or her behalf. The person

receiving the power to act on your behalf may enter into binding agreements and may create liability for you. The attorney-in-fact's power and responsibilities depend on the specific powers granted in the form. The form is used only for certain programs and actions offered by the Commodity Credit Corporation (CCC), Farm Service Agency (FSA), Natural Resources Conservation Service (NRCS), the Federal Crop Insurance Corporation (FCIC) the Risk Management Agency.

Grantors use the form of FSA–211A, Power of Attorney Signature Continuation Sheet, when the grantor is an entity, such as a general partnership, joint operation, corporation, limited liability company, or other similar entity which require more than one member's signature to appoint an attorney-in-fact to act on behalf of the entity.

Need and Use of the Information: FSA will collect information to verify an individual's authority to sign and act for another in the event of errors or fraud that requires legal remedies. The information collected on the FSA–211/211A is limited to the grantor's name, signature, and identification number, the grantee's name, address, and the applicable FSA, CCC, FCIC, NRCS, and RMA programs or transactions.

Description of Respondents: Individuals or households.

Number of Respondents: 16,000.

Frequency of Responses: Reporting: Other (once).

Total Burden Hours: 7,750.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–16842 Filed 8–4–23; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 6, 2023 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number, and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Federal Recognized State Managed Phytosanitary Program.

OMB Control Number: 0579–0365.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701–7772), the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement of plants and plant pests to prevent the introduction of plant pests into the United States or their dissemination within the United States. The Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ), has established the following procedures for States (through the National Plant Board (NPB)) to petition the Agency to recognize State-level plant pest regulations and associated action taken as meeting the international criteria for official control and accepted measures to protect areas that would be economically or environmentally endangered by the introduction of a pest. The International Plant Protection Convention (IPPC) defines ''official control'' as the active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests.

Need and Use of the Information: APHIS developed criteria by which petitions will be evaluated and status will be granted. APHIS/PPQ and the Department of Homeland Security (DHS), Customs and Border Protection (CBP), take action on imported products when quarantine pests are found upon inspection. Quarantine pests include those that pose a risk to agriculture or the environment but: (1) do not exist in the United States, (2) exist in the United States but are under Federal domestic quarantine under 7 CFR 301 or by Federal Order, (3) exist in the United States but were recently detected and whose regulatory status is under consideration, or (4) exist in the United States but are under State-level quarantine that has been approved by APHIS as providing a level of protection equivalent to a Federal domestic quarantine. APHIS has taken action on pests that meet the fourth criteria for years based on informal requests by States in the interest of supporting our State cooperators and industries within those States and this program/information collection aims to standardize this process. Without this information, APHIS would be less effective in establishing procedures that are used to contain regulated plant pests within the United States. If this information was not collected or collected less frequently, APHIS would be less effective in establishing procedures that are used to contain regulated plant pests within the United States.

Description of Respondents: State, local, or Tribal government.

Number of Respondents: 1.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 243.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–16845 Filed 8–4–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

[Docket ID FSA–2022–0014]

Notice of Funding Availability (NOFA) for the Emergency Grain Storage Facility Assistance Program (EGSFP)

AGENCY: Farm Service Agency, USDA.

ACTION: Notice of funding availability; amendment.

SUMMARY: The Farm Service Agency (FSA) is announcing an increase in the

initial funding for EGSFP to $80 million, which will be the final funding amount for the program, from the initially announced $20 million due to the high demand for EGSFP. FSA published a notice of funding availability (NOFA) notice on March 16, 2023, announcing the availability of $20 million for EGSFP. EGSFP provides financial assistance to eligible grain producers who were affected by an eligible disaster event that damaged or destroyed local commercial grain elevators. EGSFP is cost-share assistance to construct storage facilities needed to meet on-farm grain storage capacity and handling needs necessary to support the marketing of grain for producers. This notice updates the initial funding amount for the program from $20 million to $80 million and closes the application period for the program due to the current volume of applications received. This notice will not change any other information in the original EGSFP NOFA.

FOR FURTHER INFORMATION CONTACT: Danielle L. Cooke, (202) 720–1919; *Danielle.Cooke@usda.gov.* Individuals who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION: In the **Federal Register** on March 16, 2023 (88 FR 16230–16235) (referred to in this document as the March EGSFP NOFA), FSA announced the funding to implement EGSFP. At that time the funding level was announced as $20 million. FSA received a greater than expected number of applications and has not yet made any payments under EGSFP. FSA is replacing the initial funding level with a funding level of $80 million, an increase of $60 million due to the high demand for EGSFP.

EGSFP provides financial assistance to eligible grain producers who were affected by an eligible disaster event that damaged or destroyed local commercial grain elevators. EGSFP is cost-share assistance to construct storage facilities needed to meet on-farm grain storage capacity and handling needs necessary to support the marketing of grain for producers.

The Commodity Credit Corporation (CCC) is making available $80 million to FSA to provide financial assistance to grain producers through EGSFP to assist with marketing disruptions and limited storage capacity caused by eligible disaster events in affected counties from December 1, 2021, through August 1, 2022. The $80 million funding for the EGSFP assistance will remain available until expended. FSA has no plans to further increase the funding for EGSFP. Due to the high demand for EGSFP assistance and limited funding, FSA will not accept new EGSFP applications after August 7, 2023. The increased funding level announced by this notice will enable FSA to fund additional eligible applications that have already been received. However, the high demand for EGSFP assistance means that FSA will not be able to approve and fund all eligible applications that have already been received by FSA at this time and any additional applications received after this date would likewise not be funded. As explained in the March EGSFP NOFA: DAFP has the authority to modify application deadlines and other requirements or EGSFP provisions not specified in law in cases where DAFP determines it is equitable to do so and where it does not adversely affect the operation of EGSFP. Therefore, as explained above, DAFP has determined that the original application deadline has been modified and is now August 7, 2023.

This notice will not change any other information stated in the March EGSFP NOFA.

Congressional Review Act

For major rules, the Congressional Review Act requires a delay in the effective date for 60 days from the date of publication to allow for Congressional review. This NOFA is not a major rule under the Congressional Review Act, as defined by 5 U.S.C. 804(2). Therefore, this NOFA does not require a 60-day delay in implementation.

Environmental Review

The environmental impacts have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and the FSA regulations for compliance with NEPA (7 CFR part 799).

The purpose of EGSFP is to establish assistance to help agricultural producers in affected counties, including those in Illinois, Iowa, Kentucky, Minnesota, Missouri, North Dakota, South Dakota, and Tennessee, purchase and build on-farm grain storage and purchase drying and handling equipment necessary due to marketing and storage disruptions caused by devastating natural disaster events from December 1, 2021, through August 1, 2022. The limited discretionary aspects of EGSFP do not have the potential to impact the human environment as they are administrative. Accordingly, these discretionary aspects are covered by the categorical exclusions in 7 CFR 799.31(b)(6)(iii) that applies to price support programs, provided no extraordinary circumstances are found to exist. As such, the implementation of EGSFP and the participation in EGSFP do not constitute major Federal actions that would significantly affect the quality of the human environment, individually or cumulatively. Therefore, FSA will not prepare an environmental assessment or environmental impact statement for this action and this document serves as documentation of the programmatic environmental compliance decision for this Federal action.

Zach Ducheneaux,

Administrator, Farm Service Agency.

[FR Doc. 2023–16745 Filed 8–3–23; 8:45 am]

BILLING CODE 3411–E2–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Recordkeeping for Employment and Training Program Activity Report and Requests for Additional 100 Percent Funding

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection for the revision of a currently approved collection for the Supplemental Nutrition Assistance Program (SNAP) Employment and Training (E&T) Program Activity Report (form FNS–583) and State requests for additional funding. The Employment and Training Opportunities in the Supplemental Nutrition Assistance Program final rule modified the regulations to introduce priorities for reallocation of 100 percent funds and to specify that State agencies requesting additional funds should submit the requests for the upcoming fiscal year with the E&T State Plans. Requests and recordkeeping for these activities are currently approved under OMB No. 0584–0339, expiration date 03/31/2024. The burden estimate is 49.51 hours. The burden estimate is not impacted by these changes. FNS is not seeking comment on the reporting burden for the FNS–583 because that is under FNS' web-based Food Program Reporting System, OMB Control No: 0584–0594, expiration date 7/31/2023 (currently under review).

DATES: Written comments must be received on or before October 6, 2023.

ADDRESSES: Comments may be sent to: Marcie Foster, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, Alexandria, VA 22314. Comments may also be submitted via email to *marcie.foster@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Marcie Foster at 703–305–2930.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Employment and Training Program Activity Report and Requests for Additional 100 percent Funding.

Form Number: FNS–583.

OMB Number: 0584–0339.

Expiration Date: 03/31/2024.

Type of Request: Revision of a currently approved collection.

Abstract: 7 CFR 273.7(c)(9) requires State agencies to maintain quarterly E&T Program Activity Reports containing monthly figures for participation in the program. FNS uses Form FNS–583 to provide the format for this data. State agencies report this data using the online Food Program Reporting System (FPRS, OMB Control No: 0584–0594; Expiration date: 07/31/2023). State agencies must maintain records in order to support data reported in FPRS. The information collected on the FNS–583 report includes:

- On the first quarter report, the number of work registrants receiving SNAP as of October 1 of the new fiscal year;
- On each quarterly report, by month, the number of new work registrants; the number of able–bodied adults without dependents (ABAWDs) applicants and recipients participating in qualifying components; the number of all other applicants and recipients (including ABAWDs involved in non-qualifying activities) participating in components; and the number of ABAWDs exempt under the State agency's 15 percent exemption allowance;
- On the fourth quarter report, the total number of individuals, sorted by ABAWD and non-ABAWD participants, who participated in each component; the number of individuals who participated in the E&T Program during the fiscal year; the number of SNAP participants and applicants required by the State agency to participate in E&T and of those the number who began participation in an E&T program and the number who began participation in an E&T component; and number of mandatory E&T participants who were determined ineligible for failure to comply with E&T requirements. Additionally, State agencies have the option to report the number of individuals provided with case management services.

7 CFR 273.7(d)(1)(iii) provides that if a State agency will not expend all of the funds allocated to it for a fiscal year, FNS will reallocate unexpended funds to other State agencies requesting additional funds during the fiscal year or the subsequent fiscal year as FNS considers appropriate and equitable in accordance with a priority for funding requests process stipulated in 7 CFR 237.7(d)(1)(iii)(A)–(D).

7 CFR 273.7(d)(1)(iii)(E) specifies that State agencies should submit their request for additional funds with the E&T State Plans for the upcoming Federal Fiscal Year (FFY). The requests should indicate the priority category funds are requested; the amount requested; provide a detailed plan for the use of additional funds; and indicate how the use of the additional funds will support E&T programs and activities that have a demonstrable impact on the ability of participants to find and retain employment that leads to increased household income and reduced reliance on public assistance. Typically, FNS receives eighteen such requests per year. The time it takes to prepare these requests is included in the burden. After receiving the State requests, FNS will reallocate unexpended funds as provided above. The following is the estimated burden for E&T reporting including the burden for State agencies to request additional funds.

Affected Public: State, local and Tribal government. Respondent groups identified include State agencies administering the SNAP E&T program in 50 States, the District of Columbia, Guam, and the U.S. Virgin Islands.

Estimated Number of Respondents: The total estimated number of respondents annually for the recordkeeping burden of the FNS–583 is 53 State agencies, including the agencies responsible for SNAP administration in 50 States, the District of Columbia, Guam, and the U.S. Virgin Islands. The estimated number of respondents for requesting additional funds and maintaining records to support these requests is 18 per year.

Estimated Number of Responses per Respondent: The 53 States agencies are required to submit data on the FNS–583 quarterly. State agencies will be required to maintain data to support 4 reports per year.

The State agencies requesting additional funds typically do so once per year.

Estimated Total Annual Responses: 248.

Estimated Time per Response: The estimated time of response varies from 8 to 60 minutes depending on respondent group, as shown in the table below, with an average estimated time of .199 hours per response.

Estimated Total Annual Burden on Respondents: 2,971 minutes (49.51 hours). See the table below for estimated total annual burden for each type of respondent.

TOTAL ANNUAL REPORTING AND RECORDKEEPING BURDEN

[Compiling and Reporting for the FNS–583 and Requests for More Funding SNAP Employment and Training Program Activity Report]

Section of regulation	Title	Number of respondents	Reports filed annually	Total responses (C × D)	Estimated number of hours per response	Estimated total hours (C × D × F)
A	B	C	D	E	F	G
REPORTING						
7 CFR 273.7(d)(1)(i)(F)	Preparing requests for more funds after initial allocation.	18	1	18	1	18
Total Reporting Additional Funds Requests.		18	1	18	1	18
RECORDKEEPING						
7 CFR 277.12	Recordkeeping burden for FNS–583.	53	4	212	0.137	29.04
7 CFR 277.12	Recordkeeping burden for additional requests.	18	1	18	0.137	2.47
Total Recordkeeping Burden for FNS 583 and Additional Funds Requests.		53	4.34	230	0.137	31.51
SUMMARY						
Total all burdens		53	4.679	248	0.199	49.51

Tameka Owens,

Assistant Administrator, Food and Nutrition Service.

[FR Doc. 2023–16807 Filed 8–4–23; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Louisiana Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of public meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Louisiana Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold monthly business meetings on the following Tuesdays: August 15, September 19, October 17 and November 21, 2023; at 2:00 p.m. Eastern Time. The purpose of each meeting is to select a topic for the Committee's civil rights project and prepare/submit the project proposal to the Staff Director for approval. The time set aside for each meeting is 90 minutes, but each meeting may end sooner. Votes will be taken at each meeting, as needed.

DATES: Tuesdays: 8/15, 9/19, 10/17 and 11/21, 2023; 2:00 p.m. ET.

ADDRESSES: The meeting will be held via Zoom.

Meeting Link (Audio/Visual): https://www.zoomgov.com/j/1608085620

Join by Phone (Audio Only): 1–833 435 1820; Meeting ID: 160 808 5620#

FOR FURTHER INFORMATION CONTACT: Ivy Davis, Designated Federal Official at *idavis@usccr.gov* or (312) 353–8311.

SUPPLEMENTARY INFORMATION: These Committee meetings are available to the public through the meeting link above. Any interested member of the public may listen to the meetings. An open comment period will be provided to allow members of the public to make statements as time allows. Per the Federal Advisory Committee Act, public minutes of the meetings will include a list of persons who are present at the meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting ''CC'' for the meeting platform. To requesting additional accommodations, please email *csanders@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meetings. Written comments may be emailed to Ivy Davis at *idavis@usccr.gov*. Persons who desire additional information may contact the Regional Programs Coordination Unit at *ero@usccr.gov*.

Records generated from these meetings may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meetings. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Colorado Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *csanders@usccr.gov.*

Agenda

I. Welcome and Roll Call
II. Discussions to select the topic for Committee's civil rights project; once selected, to prepare/submit project proposal to Staff Director for approval.
III. Other Business
IV. Next Public Meeting
V. Public Comments
VI. Adjourn

Dated: August 1, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–16721 Filed 8–4–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual briefing.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a briefing of the Arizona Advisory Committee (Committee) to the U.S. Commission on Civil Right will convene via *ZoomGov* on Thursday, August 24, 2023, from 11 a.m.–2 p.m. Arizona Time. The purpose of the briefing is to collect testimony related to racial and ethnic disparities in pediatric healthcare in the state.

DATES: The briefing will take place on:

- Thursday, August 24, 2023, from 11 a.m.–2 p.m. Arizona Time.

ADDRESSES:

Zoom Link to Join (Audio/Visual): https://www.zoomgov.com/meeting/register/vJItduqtqD0rE4nGesqlMb5mPc5Zrgawg2w.

Telephone (Audio Only) Dial: 1–833–435–1820 (US Toll-free); Meeting ID: 160 135 6619#.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Angelica Trevino, Support Services Specialist at *atrevino@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments can be sent via email to Kayla Fajota (DFO) at *kfajota@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl2AAA.*

Please click on the ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome Remarks and Roll Call
II. Approval of Prior Minutes
III. Panelist Presentations
IV. Committee Question & Answer
V. Public Comment
VI. Adjournment

Dated: August 1, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–16718 Filed 8–4–23; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Iowa Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Iowa Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a meeting on Thursday, August 10, 2023, from 3:00 p.m.–4:00 p.m. Central Time. The Committee will hear from the University of Iowa's Scalan Center for School Mental Health to learn about civil rights concerns and mental health as they consider the potential scope of their topic of study on mental health.

DATES: The meeting will take place on Thursday, August 10, 2023, from 3:00 p.m.–4:00 p.m. Central Time.

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Video): https://bit.ly/IASACMTG.

Join by Phone (Audio Only): (833) 435–1820 USA Toll Free; Meeting ID: 161 569 3647.

FOR FURTHER INFORMATION CONTACT: Ana Fortes, Designated Federal Officer, at *afortes@usccr.gov* or (202) 681–0857.

SUPPLEMENTARY INFORMATION: This committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Corrine Sanders, Support Specialist, at *csanders@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Ana Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Iowa Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may

contact the Regional Programs Coordination Unit at *afortes@usccr.gov.*

Agenda

I. Welcome and Chair Remarks

II. Presentation

III. Committee Q&A

IV. Public Comment

V. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting due to availability of speakers and staff.

Dated: August 1, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–16723 Filed 8–4–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–25–2023]

Foreign-Trade Zone (FTZ) 7; Authorization of Production Activity; FMC Agricultural Caribe Industries, Ltd.; (Agricultural Chemicals); Manati, Puerto Rico

On April 4, 2023, FMC Agricultural Caribe Industries, Ltd., submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 7E, in Manati, Puerto Rico.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 21173, April 10, 2023). On August 2, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: August 2, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–16813 Filed 8–4–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–862]

Foundry Coke Products From the People's Republic of China: Final Results of the Expedited Fourth Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on foundry coke products (foundry coke) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable August 7, 2023.

FOR FURTHER INFORMATION CONTACT: Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2593.

SUPPLEMENTARY INFORMATION:

Background

On September 17, 2001, Commerce published the antidumping duty order on foundry coke from China.[1] On April 3, 2023, Commerce published the notice of initiation of the five-year sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On April 18, 2023, Commerce received a notice of intent to participate in this review from ABC Coke and SunCoke Energy, Inc. (collectively, domestic interested parties) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as manufacturers of a domestic like product in the United States. On May 3, 2023, the domestic interested parties provided a complete substantive response for this review within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive responses from any other interested parties, nor was a hearing requested. On May 26, 2023, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of this *Order.*

Scope of the Order

The product covered under the *Order* is coke larger than 100 mm (4 inches) in maximum diameter and at least 50 percent of which is retained on a 100 mm (4 inch) sieve, of a kind used in foundries. The foundry coke products subject to the *Order* were classifiable under subheading 2704.00.00.10 (as of January 1, 2000) and are currently classifiable under subheading 2704.00.00.11 (as of July 1, 2000) of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and Customs purposes, our written description of the scope of the *Order* is dispositive.[6]

Analysis of Comments Received

All issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the margins likely to prevail if the *Order* were revoked, are addressed in the accompanying Issues and Decision Memorandum.[7] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Foundry Coke Products from the People's Republic of China,* 66 FR 48025 (September 17, 2001) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Review,* 88 FR 19616 (April 3, 2023).

[3] *See* Domestic Interested Parties' Letter, ''Notice of Intent to Participate in the Fourth Sunset Review of the Antidumping Duty Order,'' dated April 18, 2023.

[4] *See* Domestic Interested Parties' Letter, ''Substantive Response to Notice of Initiation of the Fourth Sunset Review of the Antidumping Duty Order,'' dated May 3, 2023.

[5] *See* Commerce's Letter, ''Sunset Reviews for April 2023,'' dated May 26, 2023.

[6] For a complete description of the scope, *see* Memorandum ''Issues and Decision Memorandum for the Final Results of the Expedited Fourth Sunset Review of the Antidumping Duty Order on Foundry Coke Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *Id.*

at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 214.89 percent.

Administrative Protective Order (APO)

This notice serves as the only reminder to interested parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: August 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. History of the Order
V. Legal Framework
VI. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of Dumping
2. Magnitude of the Margins Likely To Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2023–16818 Filed 8–4–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–899]

Acetone From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that Kumho P&B Chemicals, Inc. (KPB) and LG Chem, Ltd. (LG Chem) did not make sales of subject merchandise at less than normal value during the period of review (POR) March 1, 2021, through February 28, 2022.

DATES: Applicable August 7, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Carey, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3964.

SUPPLEMENTARY INFORMATION:

Background

On April 5, 2023, Commerce published the preliminary results of the 2021–2022 administrative review of the antidumping duty order on acetone from the Republic of Korea.[1] We invited interested parties to comment on the *Preliminary Results*.[2] No interested parties submitted comments. Accordingly, Commerce made no changes to the *Preliminary Results.* Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The merchandise subject to the *Order* is acetone from Korea. The Chemical Abstracts Service (CAS) registry number for acetone is 67–64–1. The merchandise covered by the *Order* is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 2914.11.1000 and 2914.11.5000. Combinations or mixtures of acetone may enter under subheadings in Chapter 38 of the HTSUS, including, but not limited to, those under subheadings 3814.00.1000, 3814.00.2000, 3814.00.5010, and 3814.00.5090. The list of items found under these HTSUS subheadings is non-exhaustive. Although these HTSUS subheadings and CAS registry number are provided for convenience and customs purposes, the written description of the scope of this *Order* is dispositive.

A full description of the scope of the *Order* is provided in the *Preliminary Results*.[4]

Final Results of Review

We determine the following weighted-average dumping margins for the period March 1, 2021, through February 28, 2022.

Exporter	Weighted-average dumping margin (percent)
Kumho P&B Chemicals, Inc	0.00
LG Chem, Ltd	0.00

Disclosure

Because Commerce received no comments on the *Preliminary Results,* we have not modified our analysis and no decision memorandum accompanies this **Federal Register** notice. We are adopting the *Preliminary Results* as the final results of this review. Consequently, there are no new calculations to disclose in accordance with 19 CFR 351.224(b) for these final results.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Where the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), then Commerce will instruct CBP to liquidate entries without regard to antidumping duties.[5] Accordingly, because the final weighted-average dumping margin for KPB and LG Chem is zero percent, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries of subject merchandise during the POR produced by either KPB or LG Chem for which it did not know that the merchandise it sold to the intermediary (*e.g.,* reseller, trading company, or exporter) was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate (*i.e.,* 33.10 percent) [6] if there is no

[1] *See Acetone from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 20122 (April 5, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *Id.,* 88 FR at 20123.

[3] *See Acetone from Belgium, the Republic of South Africa, and the Republic of Korea: Antidumping Duty Orders,* 85 FR 17866 (March 31, 2020) (*Order*).

[4] *See Preliminary Results* PDM at 3–4.

[5] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[6] *See Order,* 85 FR at 17866.

rate for the intermediate company(ies) involved in the transaction.[7]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the company-specific cash deposit rate for KPB and LG Chem will be zero; (2) for companies not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review or a prior segment of the proceeding but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 33.10 percent, the all-others rate established in the less-than-fair-value investigation.[8] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

[7] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[8] *See Order,* 85 FR at 17866.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing the final results of this review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: August 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–16825 Filed 8–4–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–155]

Certain Pea Protein From the People's Republic of China: Initiation of Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable August 1, 2023.

FOR FURTHER INFORMATION CONTACT: Patrick Barton or T.J. Worthington, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0012 or (202) 482–4567, respectively.

SUPPLEMENTARY INFORMATION:

The Petition

On July 12, 2023, the U.S. Department of Commerce (Commerce) received a countervailing duty (CVD) petition concerning imports of certain pea protein (pea protein) from the People's Republic of China (China) filed in proper form on behalf of PURIS Proteins, LLC (the petitioner), a domestic producer of pea protein.[1] The CVD petition was accompanied by an antidumping duty (AD) petition concerning imports of pea protein from China.[2]

On July 17, 18, and 25, 2023, Commerce requested supplemental information pertaining to certain aspects of the Petition.[3] On July 18, 2023, the petitioner filed requests for extensions of time to respond to the supplemental questionnaires.[4] On July 21 and 26, 2023, the petitioner timely filed responses to these requests for additional information.[5]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Government of China (GOC) is providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of pea protein in China, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating CVD investigations, the Petition is supported by information reasonably available to the petitioner.

Commerce finds that the petitioner filed the Petition on behalf of the domestic industry because the petitioner is an interested party as defined in section 771(9)(C) of the Act.[6] Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested CVD investigation.[7]

[1] *See* Petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Pea Protein from China,'' dated July 12, 2023 (Petition).

[2] *Id.*

[3] *See* Commerce's Letter, ''Supplemental Questions,'' dated July 17, 2023 (Volume I Supplemental Questionnaire); *see also* Commerce's Letter, ''Supplemental Questions,'' dated July 18, 2023; and Memorandum, ''Phone Call with Counsel to the Petitioner,'' dated July 25, 2023 (Scope Memorandum).

[4] *See* Petitioner's Letters, ''Request for Extension to Respond to Volume I Supplemental Questionnaire,'' dated July 18, 2023; and ''Request for Extension to Respond to Volume III Supplemental Questionnaire,'' dated July 18, 2023.

[5] *See* Petitioner's Letters, ''Response of Petitioner to Volume I Supplemental Questionnaire,'' dated July 21, 2023 (General Issues Supplement); ''Response of Petitioner to Volume III Supplemental Questionnaire,'' dated July 21, 2023; and ''Certain Pea Protein from China/Petitioner's Response to Second Supplemental Questionnaire,'' dated July 26, 2023 (Scope Supplement).

[6] *See* Petition at Volume I (pages 2–3). PURIS Proteins, LLC is an interested party, as defined in sections 771(9)(C) and (D) of the Act, respectively.

[7] *See* ''Determination of Industry Support for the Petition'' section, *infra.*

Period of Investigation

Because the Petition was filed on July 12, 2023, the period of investigation (POI) is January 1, 2022, through December 31, 2022.[8]

Scope of the Investigation

The product covered by this investigation is pea protein from China. For a full description of the scope of this investigation, *see* the appendix to this notice.

Comments on Scope of the Investigation

On July 17 and 25, 2023, Commerce requested information from the petitioner regarding the proposed scope to ensure that the scope language in the Petition is an accurate reflection of the products for which the domestic industry is seeking relief.[9] On July 21 and 26, 2023, the petitioner provided clarifications and revised the scope.[10] The description of merchandise covered by this investigation, as described in the appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for parties to raise issues regarding product coverage (*i.e.,* scope).[11] Commerce will consider all scope comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information, all such factual information should be limited to public information.[12] To facilitate preparation of its questionnaires, Commerce requests that scope comments be submitted by 5 p.m. Eastern Time (ET) on August 21, 2023, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5 p.m. ET on August 31, 2023, which is ten calendar days from the initial comment deadline.

Commerce requests that any factual information that the parties consider relevant to the scope of the investigation be submitted during that time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact Commerce and request permission to submit the additional information. All scope comments must also be filed on the record of the concurrent AD investigation.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's (E&C) Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS), unless an exception applies.[13] An electronically filed document must be received successfully in its entirety by the time and date it is due.

Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified the GOC of the receipt of the Petition and provided an opportunity for consultations with respect to the Petition.[14] The GOC did not request consultations.

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[15] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[16]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigation.[17] Based on our analysis of the information submitted on the record, we have determined that pea protein, as defined in the scope, constitutes a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[18]

In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition

[8] *See* 19 CFR 351.204(b)(2).

[9] *See* Volume I Supplemental Questionnaire at 3–4; *see also* Scope Memorandum.

[10] *See* General Issues Supplement at 1–8 and Exhibits I–S2 and I–S3; *see also* Scope Supplement.

[11] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*); *see also* 19 CFR 351.312.

[12] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[13] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014), for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on using ACCESS can be found at: *https://access.trade.gov/help.aspx* and a handbook can be found at: *https://access.trade.gov/help/Handbook_on_Electronic_Filing_Procedures.pdf.*

[14] *See* Commerce's Letter, ''Countervailing Duty Petition on Certain Pea Protein from the People's Republic of China,'' dated July 13, 2023.

[15] *See* section 771(10) of the Act.

[16] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[17] *See* Petition at Volume I (pages 13–20 and Exhibits I–17 through I–26); *see also* General Issues Supplement at 9–15.

[18] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, *see* Countervailing Duty Investigation Initiation Checklist: Certain Pea Protein from the People's Republic of China (China Initiation Checklist) at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petition Covering Certain Pea Protein from the People's Republic of China (Attachment II). This checklist is dated concurrently with this notice and on file electronically via ACCESS.

with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the appendix to this notice. To establish industry support, the petitioner provided its 2022 production of the domestic like product and compared this to the estimated total 2022 production of pea protein by the U.S. industry.[19] We relied on data provided by the petitioner for purposes of measuring industry support.[20]

Our review of the data provided in the Petition, the General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.[21] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[22] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[23] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[24] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.[25]

Injury Test

Because China is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from China materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[26]

The petitioner contends that the industry's injured condition is illustrated by the adverse impact on the domestic industry's sales volumes, market share levels, and return on investments; significant volume of subject imports; underselling and price depression and/or suppression; lost sales and revenues; and layoffs.[27] We assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[28]

Initiation of CVD Investigation

Based upon the examination of the Petition and supplemental responses, we find that they meet the requirements of section 702 of the Act. Therefore, we are initiating a CVD investigation to determine whether imports of pea protein from China benefit from countervailable subsidies conferred by the GOC. Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on 23 of 25 programs alleged by the petitioner. For a full discussion of the basis for our decision to initiate an investigation of each program, *see* the China CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Respondent Selection

The petitioner identified 18 companies in China as producers and/or exporters of pea protein.[29] Commerce intends to follow its standard practice in CVD investigations and calculate company-specific subsidy rates in this investigation. In the event that Commerce determines that the number of companies is large, and it cannot individually examine each company based upon Commerce's resources, Commerce intends to select mandatory respondents based on quantity and value (Q&V) questionnaires issued to the potential respondents. Commerce normally selects mandatory respondents in CVD investigations using U.S. Customs and Border Protection (CBP) entry data for U.S. imports under the appropriate Harmonized Tariff Schedule of the United States (HTSUS) subheadings listed in the scope of the investigation. However, for this investigation, the main HTSUS subheadings under which the subject merchandise would enter (3504.00.1000, 3504.00.5000, and 2106.10.0000) are basket categories under which non-subject merchandise may enter. Therefore, we cannot rely on CBP entry data in selecting respondents. Instead, we intend to issue Q&V questionnaires to each potential respondent for which the petitioner has provided a complete address.

Exporters/producers of pea protein from China that do not receive Q&V questionnaires by mail may still submit a response to the Q&V questionnaire and can obtain the Q&V questionnaire from E&C's website at *https://www.trade.gov/ec-adcvd-case-announcements*. Responses to the Q&V questionnaire must be submitted by the relevant Chinese producers/exporters no later than 5 p.m. ET on August 15, 2023, which is two weeks from the signature date of this notice. All Q&V responses must be filed electronically via ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the deadline noted above. Commerce intends to finalize its decision regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A) of the Act and 19 CFR 351.202(f), a copy of the public version

[19] *See* Petition at Volume I (page 4 and Exhibits I–2 through I–6); *see also* General Issues Supplement at 8 and Exhibit I–S4.

[20] *See* Petition at Volume I (page 4 and Exhibits I–2 through I–6); *see also* General Issues Supplement at 8 and Exhibit I–S4. For further discussion, *see* Attachment II of the China CVD Initiation Checklist.

[21] *See* Petition at Volume I (page 4 and Exhibits I–2 through I–6); *see also* General Issues Supplement at 8 and Exhibit I–S4. For further discussion, *see* Attachment II of the China CVD Initiation Checklist.

[22] *See* Attachment II of the China CVD Initiation Checklist; *see also* section 702(c)(4)(D) of the Act.

[23] *See* Attachment II of the China CVD Initiation Checklist.

[24] *Id.*

[25] *Id.*

[26] *See* Petition at Volume I (pages 21–22 and Exhibits I–6 and I–29.

[27] *Id.* at Volume I (pages 21–41 and Exhibits I–4, I–6, I–29 through I–32, and I–34 through I–41.

[28] *See* China CVD Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Pea Protein from the People's Republic of China (Attachment III).

[29] *See* General Issues Supplement at 1 and Exhibit I–S1.

of the Petition has been provided to the GOC via ACCESS. Furthermore, to the extent practicable, Commerce will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

Commerce will notify the ITC of its initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of pea protein from China are materially injuring, or threatening material injury to, a U.S. industry.[30] A negative ITC determination will result in the investigation being terminated.[31] Otherwise, this CVD investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [32] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[33] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301.[34] For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10 a.m. ET on the due date. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; Commerce will grant untimely filed requests for the extension of time limits only in limited cases where we determine, based on 19 CFR 351.302, that extraordinary circumstances exist. Parties should review Commerce's regulations concerning factual information prior to submitting factual information in this investigation.[35]

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[36] Parties must use the certification formats provided in 19 CFR 351.303(g).[37] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305. Parties wishing to participate in this investigation should ensure that they meet the requirements of 19 CFR 351.103(d) (*e.g.,* by filing the required letters of appearance). Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[38]

This notice is issued and published pursuant to sections 702 and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: August 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The product within the scope of this investigation is high protein content (HPC) pea protein, which is a protein derived from peas (including, but not limited to, yellow field peas and green field peas) and which contains at least 65 percent protein on a dry weight basis. HPC pea protein may also be identified as, for example, pea protein concentrate, pea protein isolate, hydrolyzed pea protein, pea peptides, and fermented pea protein. Pea protein, including HPC pea protein, has the Chemical Abstracts Service (CAS) registry number 222400–29–5.

The scope covers HPC pea protein in all physical forms, including all liquid (*e.g.,* solution) and solid (*e.g.,* powder) forms, regardless of packaging or the inclusion of additives (*e.g.,* flavoring, suspension agents, preservatives).

The scope also includes HPC pea protein described above that is blended, combined, or mixed with non-subject pea protein or with other ingredients (*e.g.,* proteins derived from other sources, fibers, carbohydrates, sweeteners, and fats) to make products such as protein powders, dry beverage blends, and protein fortified beverages. For any such blended, combined, or mixed products, only the HPC pea protein component is covered by the scope of this investigation. HPC pea protein that has been blended, combined, or mixed with other products is included within the scope, regardless of whether the blending, combining, or mixing occurs in third countries.

HPC pea protein that is otherwise within the scope is covered when commingled (*i.e.,* blended, combined, or mixed) with HPC pea protein from sources not subject to this investigation. Only the subject component of the commingled product is covered by the scope.

A blend, combination, or mixture is excluded from the scope if the total HPC pea protein content of the blend, combination, or mixture (regardless of the source or sources) comprises less than 5 percent of the blend, combination, or mixture on a dry weight basis.

All products that meet the written physical description are within the scope of the investigation unless specifically excluded. The following products, by way of example, are outside and/or specifically excluded from the scope of the investigation:

• burgers, snack bars, bakery products, sugar and gum confectionary products, milk,

[30] *See* section 703(a)(1) of the Act.

[31] *Id.*

[32] *See* 19 CFR 351.301(b).

[33] *See* 19 CFR 351.301(b)(2).

[34] *See* 19 CFR 351.302.

[35] *See* 19 CFR 301; *see also Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at: *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm.*

[36] *See* section 782(b) of the Act.

[37] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at: *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[38] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

cheese, baby food, sauces and seasonings, and pet food, even when such products are made with HPC pea protein.

- HPC pea protein that has gone through an extrusion process to alter the HPC pea protein at the structural and functional level, resulting in a product with a fibrous structure which resembles muscle meat upon hydration. These products are commonly described as textured pea protein or texturized pea protein.
- HPC pea protein that has been further processed to create a small crunchy nugget commonly described as a pea protein crisp.
- protein derived from chickpeas.

The merchandise covered by the scope is currently classified under Harmonized Tariff Schedule of the United States (HTSUS) categories 3504.00.1000, 3504.00.5000, and 2106.10.0000. Such merchandise may also enter the U.S. market under HTSUS category 2308.00.9890. Although HTSUS categories and the CAS registry number are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

[FR Doc. 2023–16817 Filed 8–4–23; 8:45 a.m.]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–523–808]

Certain Steel Nails From the Sultanate of Oman: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on certain steel nails (steel nails) from the Sultanate of Oman (Oman). This review covers 17 exporters and producers from Oman. The period of review (POR) is July 1, 2021, through June 30, 2022. The sole mandatory respondent in this review is Oman Fasteners, LLC (Oman Fasteners). Commerce preliminarily determines that sales of subject merchandise have not been made below normal value (NV) by Oman Fasteners during the POR. In addition, we preliminarily find that Geekay Wires Ltd. (Geekay), Astrotech Steels Private Ltd. (Astrotech), Trinity Steel Pvt. Ltd. (Trinity), and Modern Factory for Metal Products, LLC (Modern) had no shipments during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable August 7, 2023.

FOR FURTHER INFORMATION CONTACT: Dakota Potts, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0223.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2022, Commerce published in the **Federal Register** a notice of opportunity [1] to request an administrative review of the antidumping duty (AD) Order on steel nails from Oman.[2] On September 6, 2022, in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice of initiation of an administrative review of the *Order*.[3]

On March 2, 2023, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.213(h)(2), Commerce extended the due date for the preliminary results by 118 days until July 28, 2023.[4] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5]

A list of the topics included in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The merchandise covered by the scope of this *Order* is steel nails from Oman. A complete description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[6]

Preliminary Determination of No Shipments

Based upon the no-shipment certifications received by Commerce, and our review of the U.S. Customs and Border Protection (CBP) data, we preliminary find that Geekay, Astrotech, Trinity, and Modern had no shipments during the POR. CBP did not provide any information to contradict the claims of no shipments during the POR.[7] Consistent with Commerce's practice, we will not rescind the review with respect to Geekay, Astrotech, Trinity, and Modern in these preliminary results, but rather will complete the review and issue appropriate liquidation instructions to CBP based on the final results.[8] For additional information regarding this determination, *see* the Preliminary Decision Memorandum.

Rate for Non-Examined Companies

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.'' However, section 735(c)(5)(B) of the Act provides that if the estimated weighted average dumping margins for exporters and producers individually examined are all zero, *de minimis,* or based entirely on facts available, Commerce may use any reasonable method to establish the estimated all-others rate.

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[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List,* 87 FR 39461 (July 1, 2022).

[2] *See Certain Steel Nails from the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 80 FR 39994 (July 13, 2015) (*Order*).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 54463 (September 6, 2022).

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated March 2, 2023.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2021–2022: Certain Steel Nails from the Sultanate of Oman'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *Id.*

[7] *See* Memorandum, ''No Shipment Inquiry for Various Companies During the Period 07/01/2021 Through 06/30/2022,'' {*sic*} dated July 20, 2023.

[8] *See, e.g., Welded Line Pipe from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017,* 84 FR 4046, 4047 (February 14, 2019), unchanged in *Welded Line Pipe from the Republic of Korea: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2016–2017,* 84 FR 27762 (June 14, 2019).

In this review, we have calculated a weighted-average dumping margin for the sole respondent, Oman Fasteners of zero percent. Accordingly, we have assigned to the companies not individually examined a margin of 0.00 percent, the sole margin calculated in this proceeding.[9]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) and (2) of the Act. Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, Commerce preliminarily determines that the following weighted-average dumping margin exists for the period July 1, 2021, through June 30, 2022:

Producer/exporter	Weighted-average dumping margin (percent)
Oman Fasteners, LLC	0.00
Al Ansari Teqmark, LLC	0.00
Al Kiyumi Global LLC	0.00
Al Sarah Building Materials LLC	0.00
Buraimi Iron & Steel, LLC	0.00
CL Synergy (Pvt) Ltd	0.00
Diamond Foil Trading LLC	0.00
Gulf Nails Manufacturing, LLC	0.00
Gulf Steel Manufacturers, LLC	0.00
Muscat Industrial Company, LLC	0.00
Muscat Nails Factory Golden Asset Trade, LLC	0.00
Omega Global Uluslararasi Tasimacilik Lojistik Ticaret Ltd. Sti	0.00
WWL Indian Private Ltd	0.00

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify certain information reported by Oman Fasteners prior to issuing its final results.

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results.[10] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs containing issues pertaining to Oman Fasteners to Commerce no later than seven days after the date on which the verification report is issued in this administrative review. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[11] Interested parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[12] Executive summaries should be limited to five pages total, including footnotes. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[13]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice. Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b). If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for an importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1). Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries of subject merchandise during the POR produced by an individually examined respondent for which it did not know its merchandise was destined for the United States, we intend to instruct CBP to liquidate such entries at the all-others rate (*i.e.,* 9.10 percent) if there is no rate for the intermediate company(ies) involved in the transaction.[14]

If we continue to find in the final results that Geekay, Astrotech, Trinity, and Modern had no shipments of subject merchandise during the POR, we will instruct CBP to liquidate any suspended entries that entered under their antidumping duty case numbers (*i.e.,* at that exporter's rate) at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of steel nails from Oman entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Oman Fasteners will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate

[9] *See Albemarle Corp. & Subsidiaries* v. *United States,* 821 F.3d 1345, 1353 (Fed. Cir. 2016); *see also Certain Hot Rolled Steel Flat Products from Japan: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2017–2018,* 85 FR 57821 (September 16, 2020).

[10] *See* 19 CFR 351.224(b).

[11] *See* 19 CFR 351.309(d); *see also* Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19, 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect).'').

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension Effective Period,* 85 FR 41363 (July 10, 2020) (Temporary Rule).

[14] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other producers or exporters is 9.10 percent.[15] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: July 28, 2023.

Lisa. W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Preliminary Determination of No Shipments
V. Companies not Selected for Individual Examination
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

[FR Doc. 2023–16823 Filed 8–4–23; 8:45 am]

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[15] *See Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–153; C–533–918]

Certain Paper Shopping Bags From the People's Republic of China and India: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable August 7, 2023.

FOR FURTHER INFORMATION CONTACT: Seth Brown (the People's Republic of China (China)) and Paul Kebker (India), AD/CVD Operations, Offices IX and IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0029 or (202) 482–2254, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 20, 2023, the U.S. Department of Commerce (Commerce) initiated countervailing duty (CVD) investigations of imports of certain paper shopping bags (paper bags) from China and India.[1] Currently, the preliminary determinations are due no later than August 24, 2023.

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny it.

On July 27, 2023, the petitioner submitted timely requests that Commerce postpone the preliminary determinations in these investigations.[2] The petitioner stated that, because the mandatory respondents have not yet submitted their initial questionnaire responses, additional time is needed to identify deficiencies in advance of the preliminary determinations so that Commerce can issue supplemental questionnaires.[3]

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determinations, and Commerce finds no compelling reason to deny the requests. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations to no later than 130 days after the date on which this investigation was initiated, *i.e.,* October 30, 2023.[4] Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: August 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–16824 Filed 8–4–23; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Paper Shopping Bags from India and the People's Republic of China: Initiation of Countervailing Duty Investigations,* 88 FR 41380 (June 26, 2023) (*Initiation Notice*).

[2] *See* Petitioner's Letters, ''Petitioner's Request for Extension Preliminary Determination Deadline,'' dated July 27, 2023. The petitioner is the Coalition for Fair Trade in Shopping Bags the members of which are Novolex Holdings, LLC and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC.

[3] *Id.*

[4] Because the extended deadline for these preliminary determinations falls on the weekend (*i.e.,* October 28, 2023), the deadline becomes the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–849, A–552–812]

Steel Wire Garment Hangers From Taiwan and the Socialist Republic of Vietnam: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) orders on steel wire garment hangers (hangers) from Taiwan and the Socialist Republic of Vietnam (Vietnam) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable August 7, 2023.

FOR FURTHER INFORMATION CONTACT: Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2593.

SUPPLEMENTARY INFORMATION:

Background

On December 10, 2012, and February 5, 2013, Commerce published the AD orders on hangers from Taiwan and Vietnam, respectively.[1] On April 3, 2023, Commerce published the notice of initiation of the five-year sunset review of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On April 11, 2023, Commerce received a notice of intent to participate in this review from M&B Metal Products Company, Inc. (domestic interested party) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act as a manufacturer of a domestic like product in the United States. On April 13, 2023, the domestic interested party provided a complete substantive response for this review within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive responses from any other interested parties, nor was a hearing requested. On April 24, 2023, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Orders.*

Scope of the Orders

The merchandise subject to the *Orders* are steel wire garment hangers, fabricated from carbon steel wire, whether or not galvanized or painted, whether or not coated with latex or epoxy or similar gripping materials, and whether or not fashioned with paper covers or capes (with or without printing) or nonslip features such as saddles or tubes. These products may also be referred to by a commercial designation, such as shirt, suit, strut, caped, or latex (industrial) hangers. The products subject to the *Orders* are currently classified under U.S. Harmonized Tariff Schedule (HTSUS) subheadings 7326.20.0020 and 7323.99.9080. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive. A full description of the scope of the *Orders* is contained in the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the margins likely to prevail if the *Order* were revoked, are addressed in the Issues and Decision Memorandum.[7] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(c) of the Act, Commerce determines that revocation of the *Orders* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be up to 125.43 percent for Taiwan and up to 220.63 percent for Vietnam.

Administrative Protective Order

This notice serves as the only reminder to interested parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: August 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Orders*
IV. History of the *Orders*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins of Dumping Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2023–16819 Filed 8–4–23; 8:45 am]

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[1] *See Steel Wire Garment Hangers from Taiwan: Antidumping Duty Order,* 77 FR 73424 (December 10, 2012); and *Steel Wire Garment Hangers from the Socialist Republic of Vietnam: Antidumping Duty Order,* 78 FR 8105 (February 5, 2013) (collectively, *Orders*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 19616 (April 3, 2023).

[3] *See* Domestic Interested Party's Letter, ''Notice of Intent to Participate,'' dated April 11, 2023.

[4] *See* Domestic Interested Party's Letter, ''Five-Year (Sunset) Review of Steel Wire Garment Hangers from Taiwan-Substantive Response of Domestic Producer to Notice of Initiation,'' dated April 13, 2023; *see also* Domestic Interested Party's Letter, ''Five-Year (Sunset) Review of Steel Wire Garment Hangers from Vietnam (AD)-Substantive Response of Domestic Producer to Notice of Initiation,'' dated April 13, 2023.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on April 3, 2023,'' dated April 24, 2023.

[6] *See* Memorandum, ''Issues and Decisions Memorandum for the Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order on Steel Wire Garment Hangers from Taiwan and the Socialist Republic of Vietnam,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decisions Memorandum).

[7] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–154]

Certain Pea Protein From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable August 1, 2023.

FOR FURTHER INFORMATION CONTACT: Rebecca Janz or Ann Marie Caton, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2972 or (202) 482–2607, respectively.

SUPPLEMENTARY INFORMATION:

The Petition

On July 12, 2023, the U.S. Department of Commerce (Commerce) received an antidumping duty (AD) petition concerning imports of certain pea protein (pea protein) from the People's Republic of China (China) filed in proper form on behalf of PURIS Proteins, LLC (the petitioner), a U.S. producer of pea protein.[1] The Petition was accompanied by a countervailing duty (CVD) petition concerning imports of pea protein from China.[2]

On July 17 and 25, 2023, Commerce requested supplemental information pertaining to certain aspects of the Petition.[3] On July 21 and 26, 2023, the petitioner filed timely responses to these requests for additional information.[4]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of pea protein from China are being, or are likely to be, sold in the United States at less than fair value (LTFV) within the meaning of section 731 of the Act, and that imports of such pea protein are materially injuring, or threatening material injury to, the pea protein industry in the United States. Consistent with section 732(b)(1) of the Act, the Petition is accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the Petition was filed on behalf of the domestic industry because the petitioner is an interested party, as defined in section 771(9)(C) of the Act. Commerce also finds that the petitioner demonstrated sufficient industry support for the initiation of the requested AD investigation.[5]

Period of Investigation

Because China is a non-market economy (NME) country, pursuant to 19 CFR 351.204(b)(1), the period of investigation (POI) is January 1, 2023, through June 30, 2023.

Scope of the Investigation

The product covered by this investigation is pea protein from China. For a full description of the scope of this investigation, *see* the appendix to this notice.

Comments on the Scope of the Investigation

On July 17 and 25, 2023, Commerce requested information from the petitioner regarding the proposed scope to ensure that the scope language in the Petition is an accurate reflection of the products for which the domestic industry is seeking relief.[6] On July 21 and 26, 2023, the petitioner provided clarifications and revised the scope.[7] The description of merchandise covered by this investigation, as described in the appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for parties to raise issues regarding product coverage (*i.e.,* scope).[8] Commerce will consider all scope comments received and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that scope comments be submitted by 5 p.m. Eastern Time (ET) on August 21, 2023, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5 p.m. ET on August 31, 2023, which is ten calendar days from the initial comment deadline.

Commerce requests that any factual information that parties consider relevant to the scope of this investigation be submitted during that period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party must contact Commerce and request permission to submit the additional information. All such submissions must be filed on the record of the concurrent CVD investigation.

Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS), unless an exception applies.[10] An electronically filed document must be received successfully in its entirety by the time and date it is due.

Comments on Product Characteristics

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of pea protein to be reported in response to Commerce's AD questionnaire. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors of production (FOPs) accurately, as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics.

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[1] *See* Petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Pea Protein from China,'' dated July 11, 2023 (Petition).

[2] *Id.*

[3] *See* Commerce's Letters, ''Petition for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Pea Protein from the People's Republic of China: Supplemental Questions,'' dated July 17, 2023; ''Petition for the Imposition of Antidumping Duties on Imports of Certain Pea Protein from the People's Republic of China: Supplemental Questions,'' dated July 17, 2023; *see also* Memorandum, ''Phone Call with Counsel to the Petitioner,'' dated July 25, 2023 (Memorandum to the File on Scope).

[4] *See* Petitioner's Letter, ''Antidumping and Countervailing Duties on Imports of Certain Pea Protein from China: Response of Petitioner to Volume I of Supplemental Questionnaire,'' dated July 21, 2023 (China AD Supplement); *see also* Petitioner's Letter, ''Certain Pea Protein from China/Petitioner's Response to Second Supplemental Questionnaire,'' dated July 26, 2023 (Scope Supplement).

[5] *See* ''Determination of Industry Support for the Petitions'' section, *infra.*

[6] *See* General Issues Questionnaire at 3–4; *see also* Memorandum to the File on Scope.

[7] *See* General Issues Supplement at 2–8 and Exhibit I–S3; *see also* Scope Supplement.

[8] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*); *see also* 19 CFR 351.312.

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance: Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook_on_Electronic_Filing_Procedures.pdf.*

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaire, all product characteristics comments must be filed by 5 p.m. ET on August 21, 2023, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5 p.m. ET on August 31, 2023, which is 10 calendar days after the initial comment deadline. All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above, on the record of the AD investigation.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[11] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[12]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigation.[13] Based on our analysis of the information submitted on the record, we have determined that pea protein, as defined in the scope, constitutes a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[14]

In determining whether the petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the appendix to this notice. To establish industry support, the petitioner provided its 2022 production of the domestic like product and compared this to the estimated total 2022 production of pea protein by the U.S. industry.[15] We relied on data provided by the petitioner for purposes of measuring industry support.[16]

Our review of the data provided in the Petition, the General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.[17] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product, and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[18] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[19] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[20] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.[21]

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[22]

The petitioner contends that the industry's injured condition is illustrated by the adverse impact on the domestic industry's sales volumes, market share levels, and return on investments; significant volume of subject imports; underselling and price depression and/or suppression; lost sales and revenues; and layoffs.[23] We

[11] *See* section 771(10) of the Act.

[12] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[13] *See* Petition at Volume I (pages 13–20 and Exhibits I–17 through I–27); *see also* General Issues Supplement at 9–15.

[14] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, *see* Antidumping Duty Investigation Initiation Checklist: Certain Pea Protein from the People's Republic of China (China AD Initiation Checklist) at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Pea Protein from the People's Republic of China (Attachment II). This checklist is dated concurrently with this notice and on file electronically via ACCESS.

[15] *See* Petition at Volume I (page 4 and Exhibits I–2 through I–6); *see also* General Issues Supplement at 8 and Exhibit I–S4.

[16] *See* Petition at Volume I (page 4 and Exhibits I–2 through I–6); *see also* General Issues Supplement at 8 and Exhibit I–S4. For further discussion, *see* Attachment II of the China AD Initiation Checklist.

[17] *See* Petition at Volume I (page 4 and Exhibits I–2 through I–6); *see also* General Issues Supplement at 8 and Exhibit I–S4. For further discussion, *see* Attachment II of the China AD Initiation Checklist.

[18] *See* Attachment II of the China AD Initiation Checklist; *see also* section 732(c)(4)(D) of the Act.

[19] *See* Attachment II of the China AD Initiation Checklist.

[20] *Id.*

[21] *Id.*

[22] *See* Petition at Volume I (pages 21–22 and Exhibits I–6 and I–29).

[23] *Id.* at Volume I (pages 21–41 and Exhibits I–4, I–6, I–29 through I–32, and I–34 through I–41).

assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.[24]

Allegations of Sales at LTFV

The following is a description of the allegation of sales at LTFV upon which Commerce based its decision to initiate an AD investigation of imports of pea protein from China. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the China AD Initiation Checklist.

U.S. Price

The petitioner based export price (EP) on a transaction-specific average unit value (AUV) (*i.e.,* a month and port-specific AUV) derived from official import data and tied to ship manifest data. The petitioner made certain adjustments to this U.S. price to calculate a net ex-factory U.S. price.[25]

The petitioner also based EPs on pricing information for sales of, or offers for sale of, pea protein produced in and exported from China. The petitioner made certain adjustments to these U.S. prices to calculate a net ex-factory U.S. price, where applicable.[26]

Normal Value

Commerce considers China to be an NME country.[27] In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by Commerce. Therefore, we continue to treat China as an NME country for purposes of the initiation of this investigation. Accordingly, NV in China is appropriately based on FOPs valued in a surrogate market economy country, in accordance with section 773(c) of the Act.

The petitioner states that the Republic of Turkey (Turkey) is an appropriate surrogate country because Turkey is a market economy country that is at a level of economic development comparable to that of China and a significant producer of comparable merchandise.[28] The petitioner submitted publicly-available information from Turkey to value all FOPs.[29] Based on the information provided by the petitioner, we determine that it is appropriate to use Turkey as a surrogate country for China for initiation purposes.

Interested parties will have the opportunity to submit comments regarding surrogate country selections and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value FOPs within 30 days before the scheduled date of the preliminary determination.

Factors of Production

The petitioner used the product-specific consumption rates of a U.S. producer of pea protein as a surrogate to value Chinese manufacturers' FOPs.[30] Additionally, the petitioner calculated factory overhead; selling, general and administrative expenses; and profit based on the experience of a Turkish producer of comparable merchandise (*i.e.,* milled food products).[31]

Fair Value Comparisons

Based on the data provided by the petitioner, there is reason to believe that imports of pea protein from China are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of EP to NV, in accordance with sections 772 and 773 of the Act, the estimated dumping margins for pea protein range from 18.48 percent to 280.31 percent *ad valorem*.[32]

Initiation of LTFV Investigation

Based upon the examination of the Petition and supplemental responses, we find that the Petition meets the requirements of section 732 of the Act. Therefore, we are initiating an AD investigation to determine whether imports of pea protein from China are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

Respondent Selection

In the Petition, the petitioner named 18 companies in China as producers and/or exporters of pea protein.[33] In accordance with our standard practice for respondent selection in AD investigations involving NME countries, Commerce selects respondents based on quantity and value (Q&V) questionnaires in cases where it determines that the number of companies is large and it cannot individually examine each company based upon its resources. Therefore, considering the number of producers and/or exporters identified in the Petition, Commerce will solicit Q&V information that can serve as a basis for selecting exporters for individual examination in the event that Commerce decides to limit the number of respondents individually examined pursuant to section 777A(c)(2) of the Act. Because there are 18 Chinese producers and/or exporters identified in the Petition, Commerce has determined that it will issue Q&V questionnaires to each potential respondent for which the petitioner has provided a complete address.

In addition, Commerce will post the Q&V questionnaires along with filing instructions on Commerce's website at *https://www.trade.gov/ec-adcvd-case-announcements.* Producers/exporters of pea protein from China that do not receive Q&V questionnaires may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Commerce's website. In accordance with the standard practice for respondent selection in AD cases involving NME countries, in the event Commerce decides to limit the number of respondents individually investigated, Commerce intends to base respondent selection on the responses to the Q&V questionnaire that it receives.

Responses to the Q&V questionnaire must be submitted by the relevant Chinese producers/exporters no later than 5 p.m. ET on August 15, 2023, which is two weeks from the signature date of this notice. All Q&V questionnaire responses must be filed electronically via ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the deadline noted above.

Interested parties must submit applications for disclosure under

[24] *See* China AD Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Pea Protein from the People's Republic of China.

[25] *See* China AD Initiation Checklist.

[26] *Id.*

[27] *See, e.g., Antidumping Duty Investigation of Certain Aluminum Foil from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value and Postponement of Final Determination,* 82 FR 50858, 50861 (November 2, 2017), and accompanying Preliminary Decision Memorandum at ''China's Status as a Non-Market Economy,'' unchanged in *Certain Aluminum Foil from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 83 FR 9282 (March 5, 2018).

[28] *See* Petition at Volume II at 3–4.

[29] *Id.* at 4–6 and Exhibit II–12.

[30] *See* Petition at Volume I at 8 and Exhibits I–6, I–17, and I–18; *see* also Petition at Volume II at 4 and Exhibit II–13.

[31] *See* Petition at Volume II at 4–6 and Exhibit II–12.

[32] *See* China AD Initiation Checklist for details of the calculations.

[33] *See* China AD Supplement at 1 and Exhibit I–S1.

administrative protective order in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on Commerce's website at *https://www.trade.gov/administrative-protective-orders.* Commerce intends to make its decisions regarding respondent selection within 20 days of publication of this notice.

Separate Rates

In order to obtain separate rate status in an NME investigation, exporters and producers must submit a separate rate application. The specific requirements for submitting a separate rate application in an NME investigation are outlined in detail in the application itself, which is available on Commerce's website at *https://access.trade.gov/Resources/nme/nme-sep-rate.html.* The separate rate application will be due 30 days after publication of this initiation notice. Exporters and producers who submit a separate rate application and are selected as mandatory respondents will be eligible for consideration for separate rate status only if they respond to all parts of Commerce's AD questionnaire as mandatory respondents. Commerce requires that companies from China submit a response both to the Q&V questionnaire and to the separate rate application by the respective deadlines in order to receive consideration for separate rate status. Companies not filing a timely Q&V questionnaire response will not receive separate rate consideration.

Use of Combination Rates

Commerce will calculate combination rates for certain respondents that are eligible for a separate rate in an NME investigation. The Separate Rates and Combination Rates Bulletin states:

> {w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that {Commerce} will now assign in its NME Investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the {weighted average} of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question *and* produced by a firm that supplied the exporter during the period of investigation.[34]

Distribution of Copies of the AD Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petition have been provided to the government of China, via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the AD Petition to each exporter named in the AD Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

Commerce will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of pea protein from China are materially injuring, or threatening material injury to, a U.S. industry.[35] A negative ITC determination will result in the investigation being terminated.[36] Otherwise, this AD investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [37] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[38] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, standalone submission; under limited circumstances, Commerce will grant untimely filed requests for the extension of time limits, where we determine, based on 19 CFR 351.302, that extraordinary circumstances exist. Parties should review Commerce's regulations concerning the extension of time limits and the *Time Limits Final Rule* prior to submitting factual information in this investigation.[39]

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[40] Parties must use the certification formats provided in 19 CFR 351.303(g).[41] Commerce intends to reject factual submissions if the

[34] *See* Enforcement and Compliance's Policy Bulletin 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigation involving NME Countries,'' (April 5, 2005) at 6 (emphasis added), available on Commerce's website at *https://access.trade.gov/Resources/policy/bull05-1.pdf.*

[35] *See* section 733(a) of the Act.

[36] *Id.*

[37] *See* 19 CFR 351.301(b).

[38] *See* 19 CFR 351.301(b)(2).

[39] *See* 19 CFR 351.302; *see also Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013) (*Time Limits Final Rule*), available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm.*

[40] *See* section 782(b) of the Act.

[41] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*). Answers to frequently asked questions regarding the *Final Rule* are available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305. Parties wishing to participate in this investigation should ensure that they meet the requirements of 19 CFR 351.103(d) (*e.g.,* by filing the required letter of appearance).[42] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[43]

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: August 1, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The product within the scope of this investigation is high protein content (HPC) pea protein, which is a protein derived from peas (including, but not limited to, yellow field peas and green field peas) and which contains at least 65 percent protein on a dry weight basis. HPC pea protein may also be identified as, for example, pea protein concentrate, pea protein isolate, hydrolyzed pea protein, pea peptides, and fermented pea protein. Pea protein, including HPC pea protein, has the Chemical Abstracts Service (CAS) registry number 222400–29–5.

The scope covers HPC pea protein in all physical forms, including all liquid (*e.g.,* solution) and solid (*e.g.,* powder) forms, regardless of packaging or the inclusion of additives (*e.g.,* flavoring, suspension agents, preservatives).

The scope also includes HPC pea protein described above that is blended, combined, or mixed with non-subject pea protein or with other ingredients (*e.g.,* proteins derived from other sources, fibers, carbohydrates, sweeteners, and fats) to make products such as protein powders, dry beverage blends, and protein fortified beverages. For any such blended, combined, or mixed products, only the HPC pea protein component is covered by the scope of this investigation. HPC pea protein that has been blended, combined, or mixed with other products is included within the scope, regardless of whether the blending, combining, or mixing occurs in third countries.

HPC pea protein that is otherwise within the scope is covered when commingled (*i.e.,* blended, combined, or mixed) with HPC pea protein from sources not subject to this investigation. Only the subject component of the commingled product is covered by the scope.

A blend, combination, or mixture is excluded from the scope if the total HPC pea protein content of the blend, combination, or mixture (regardless of the source or sources) comprises less than five percent of the blend, combination, or mixture on a dry weight basis.

All products that meet the written physical description are within the scope of the investigation unless specifically excluded. The following products, by way of example, are outside and/or specifically excluded from the scope of the investigation:

- burgers, snack bars, bakery products, sugar and gum confectionary products, milk, cheese, baby food, sauces and seasonings, and pet food, even when such products are made with HPC pea protein.
- HPC pea protein that has gone through an extrusion process to alter the HPC pea protein at the structural and functional level, resulting in a product with a fibrous structure which resembles muscle meat upon hydration. These products are commonly described as textured pea protein or texturized pea protein.
- HPC pea protein that has been further processed to create a small crunchy nugget commonly described as a pea protein crisp.
- protein derived from chickpeas.

The merchandise covered by the scope is currently classified under Harmonized Tariff Schedule of the United States (HTSUS) categories 3504.00.1000, 3504.00.5000, and 2106.10.0000. Such merchandise may also enter the U.S. market under HTSUS category 2308.00.9890. Although HTSUS categories and the CAS registry number are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

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[42] *See Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008).

[43] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–833]

Citric Acid and Certain Citrate Salts From Thailand: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Sunshine Biotech International Co., Ltd. made sales of subject merchandise at less than normal value (NV) during the July 1, 2021, through June 30, 2022, period of review (POR) and that COFCO Biochemical (Thailand) Co., Ltd. did not.

DATES: Applicable August 7, 2023.

FOR FURTHER INFORMATION CONTACT: Joy Zhang or Alex Cipolla, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1168 or (202) 482–4956, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 7, 2023, Commerce published the *Preliminary Results.*[1] We invited interested parties to comment on the *Preliminary Results.*[2] No interested party submitted comments on the *Preliminary Results.* Accordingly, the final results remain unchanged from the *Preliminary Results.* Commerce conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The scope of the *Order* includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend.

The scope also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the production of citric acid, sodium citrate, and potassium citrate.

The scope includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively.

The scope does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia

[1] *See Citric Acid and Certain Citrate Salts from Thailand: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 20856 (April 7, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See Preliminary Results,* 88 FR at 20857.

[3] *See Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018) (*Order*).

and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product. Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and, if included in a mixture or blend, 3824.99.9295 of the HTSUS. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.99.9295 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Final Results of the Review

We determine that the following weighted-average dumping margins exist for the period July 1, 2021, through June 30, 2022:

Producer or exporter	Weighted-average dumping margin (percent)
COFCO Biochemical (Thailand) Co., Ltd. (COFCO) ...	0.00
Sunshine Biotech International Co., Ltd	0.78
Xitrical Group Co., Ltd	0.78

Disclosure and Public Comment

As noted above, Commerce received no comments on its *Preliminary Results.* As a result, we have not modified our analysis, and will not issue a decision memorandum to accompany this **Federal Register** notice. Further, because we have not changed our calculations since the *Preliminary Results,* there are no new calculations to disclose in accordance with 19 CFR 351.224(b) for these final results. We are adopting the *Preliminary Results* as the final results.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. We will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of the importer's sales in accordance with 19 CFR 351.212(b)(1).

Where the respondent's weighted-average dumping margin is either zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's ''reseller policy'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[4]

The assessment rate for the company not selected for individual examination (*i.e.,* Xitrical Group Co. Ltd.) will be equal to the weighted-average dumping margin identified in the final results of review.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not covered in this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the less-than-fair-value (LTFV) investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 11.25 percent, the all-others rate established in the LTFV investigation.[5] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this period of review. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: July 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–16820 Filed 8–4–23; 8:45 am]

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[4] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[5] *See Order,* 83 FR at 35214.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD190]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Habitat Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This meeting will be held in-person with a webinar option. Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, August 24, 2023, at 9 a.m.

ADDRESSES:

Meeting address: This meeting will be held at the Four Points by Sheraton, One Audubon Road, Wakefield, MA 01880; telephone: (781) 245–9300.

Webinar registration URL information: https://attendee.gotowebinar.com/register/956484289127045982.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will review draft alternatives for the Northern Edge Habitat Scallop Framework. They plan to discuss progress towards completion of the Council's 5-year EFH review. The committee will also receive updates from Council staff on recent coordination with BOEM and NOAA related to offshore wind leasing in the Gulf of Maine, and on other offshore wind issues. They also plan to develop a list of habitat work priorities for 2024. In addition to habitat actions, the Committee should identify offshore wind and aquaculture-related work items. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 2, 2023.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–16839 Filed 8–4–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD219]

Endangered Species; File No. 23200

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for a permit modification.

SUMMARY: Notice is hereby given that Frederick Scharf, Ph.D., University of North Carolina Wilmington, 601 S. College Road, Wilmington, NC 28403, has requested a modification to scientific research Permit No. 23200–01.

DATES: Written comments must be received on or before September 6, 2023.

ADDRESSES: The modification request and related documents are available for review by selecting ''Records Open for Public Comment'' from the Features box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 23200 Mod 6 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 23200 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Erin Markin, Ph.D., or Malcolm Mohead, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject modification to Permit No. 23200–01, issued on January 24, 2022 (87 FR 7820, February 10, 2022) is requested under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Permit No. 23200–01 authorizes the permit holder to: conduct scientific research on adult, subadult, and juvenile Atlantic (*Acipenser oxyrinchus*) and shortnose (*A. brevirostrum*) sturgeon to determine their abundance, distribution, habitat use, and migration dynamics in the coastal rivers and estuaries of North Carolina basins (Cape Fear, Neuse, Tar/Pamlico, Roanoke/Chowan). Researchers may capture Atlantic and shortnose sturgeon using gill nets, trammel nets, or trawls, measure, weigh, mark (passive integrated transponder (PIT), Floy), biologically sample (tissue), anesthetize, acoustically tag, and photograph/video sturgeon prior to release. The permit holder requests authorization to: (1) increase the number of juvenile, subadult, and adult Atlantic sturgeon to receive an internal acoustic tag; (2) add external acoustic tagging of Atlantic sturgeon; and (3) conduct research on Atlantic sturgeon captured under other authority in the Frying Pan Shoals area. Up to 5 additional subadult/adult and up to 20 juvenile Atlantic sturgeon would receive an internal acoustic tagging annually in each location. Up to 75 subadult/adult and 50 juvenile Atlantic sturgeon may be captured under other authority during surveys in the Frying Pan Shoals area. Sturgeon captured under other authority may be marked (PIT, Floy), biologically sampled (tissue), measured, weighed, and photographed/videoed prior to release. A subset may receive either an external or internal acoustic tag prior to release. The permit is valid through January 31, 2025.

Dated: August 1, 2023.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–16808 Filed 8–4–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–C–2023–0029]

Performance Review Board

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: In conformance with the Civil Service Reform Act of 1978, the United States Patent and Trademark Office (USPTO) announces the appointment of persons to serve as members of its Performance Review Board (PRB).

ADDRESSES: Office of Human Resources, USPTO, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Lari B. Washington, Director, Human Capital Management, USPTO, at 571–272–5187.

SUPPLEMENTARY INFORMATION: The membership of the USPTO PRB is as follows:

Derrick Brent, Chair, Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the USPTO
Frederick W. Steckler, Vice Chair, Chief Administrative Officer, USPTO
Vaishali Udupa, Commissioner for Patents, USPTO
David S. Gooder, Commissioner for Trademarks, USPTO
Dennis J. Hoffman, Chief Financial Officer, USPTO
Henry J. Holcombe, Chief Information Officer, USPTO
David L. Berdan, General Counsel, USPTO
Mary Critharis, Chief Policy Officer and Director for International Affairs, USPTO
Gerard F. Rogers, Chief Administrative Trademark Judge, USPTO
Scott R. Boalick, Chief Administrative Patent Judge, USPTO
Bismarck Myrick, Director of the Office of Equal Employment Opportunity and Diversity, USPTO
Cara Duckworth, Chief Corporate Communications Officer, USPTO
Shirin Bidel-Niyat, Chief of Staff, USPTO

Alternates:

Robin Evans, Deputy Commissioner for Patents, USPTO
Amy Cotton, Deputy Commissioner for Trademark Examination Policy, USPTO

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2023–16815 Filed 8–4–23; 8:45 am]

BILLING CODE 3510–16–P

CONSUMER FINANCIAL PROTECTION BUREAU

Supervisory Highlights, Issue 30, Summer 2023

AGENCY: Consumer Financial Protection Bureau.

ACTION: Supervisory Highlights.

SUMMARY: The Consumer Financial Protection Bureau (CFPB or Bureau) is issuing its thirtieth edition of Supervisory Highlights.

DATES: The Bureau released this edition of the Supervisory Highlights on its website on July 26, 2023. The findings included in this report cover examinations in the areas of auto origination, auto servicing, consumer reporting, debt collection, deposits, fair lending, information technology, mortgage origination, mortgage servicing, payday and small dollar lending, and remittances that were completed from July 1, 2022, to March 31, 2023.

FOR FURTHER INFORMATION CONTACT: Jaclyn Sellers, Senior Counsel, at (202) 435–7449. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

1. Introduction

Since its inception, the Consumer Financial Protection Bureau's (CFPB's) Supervision program has assessed supervised institutions' compliance with Federal consumer financial law and taken supervisory action against institutions that have violated it.[1] This includes institutions engaged in unfair, deceptive, or abusive acts or practices (UDAAPs) prohibited by the Consumer Financial Protection Act of 2010 (CFPA).[2] In April 2023, the CFPB issued a policy statement on abusive acts or practices to summarize the existing precedent, provide an analytical framework for identifying abusive conduct, and to offer some guiding principles.[3]

This edition of *Supervisory Highlights* notes recent supervisory findings of abusive acts or practices supervised institutions engaged in across multiple product lines. Examiners also continue to find that supervised institutions are engaging in prohibited unfair and deceptive acts or practices. The CFPB will continue to supervise for, and enforce against, practices that may violate Federal consumer financial law, harm consumers, and impede competition.

Most supervised institutions rely on technology solutions to run their businesses and offer or provide consumer financial products or services. Supervision assesses information technology utilized by supervised entities, and information technology controls, that may impact compliance with Federal consumer financial law or risk to consumers. Examiners have identified several violations of Federal consumer financial law that were caused in whole or in part by insufficient information technology controls. This edition includes for the first time, findings from the CFPB's Supervision information technology program.

A key aspect of the CFPB supervision program is benefitting supervised institutions by identifying compliance issues before they become significant. The supervision process is confidential in nature. This confidentiality promotes candid communication between supervised institutions and CFPB supervisory personnel concerning compliance and related matters.

The findings included in this report cover examinations in the areas of auto origination, auto servicing, consumer reporting, debt collection, deposits, fair lending, information technology, mortgage origination, mortgage servicing, payday and small dollar lending, and remittances that were completed from July 1, 2022, to March 31, 2023. To maintain the anonymity of the supervised institutions discussed in *Supervisory Highlights,* references to institutions generally are in the plural and related findings may pertain to one or more institutions.

2. Supervisory Observations

2.1 Auto Origination

The CFPB assessed the auto finance origination operations of several

[1] If a supervisory matter is referred to the Office of Enforcement, Enforcement may cite additional violations based on these facts or uncover additional information that could impact the conclusion as to what violations may exist.

[2] 12 U.S.C. 5531, 5536.

[3] CFPB Policy Statement on Abusive Acts or Practices, *available at https://www.consumerfinance.gov/compliance/supervisory-guidance/policy-statement-on-abusiveness/.*

supervised institutions for compliance with applicable Federal consumer financial laws and to assess whether institutions have engaged in UDAAPs prohibited by the CFPA.[4]

2.1.1 Deceptive Marketing of Auto Loans

Examiners found that supervised institutions engaged in the deceptive marketing of auto loans when they used advertisements that pictured cars that were significantly larger, more expensive, and newer than the advertised loan offers were good for. An act or practice is deceptive when: (1) the representation, omission, act, or practice misleads or is likely to mislead the consumer; (2) the consumer's interpretation of the representation, omission, act, or practice is reasonable under the circumstances; and (3) the misleading representation, omission, act, or practice is material.[5]

Examiners found that the representations made in these advertisements were likely to mislead consumers, as the ''net impression'' to consumers was that the advertisements applied to a subset of cars to which they did not actually apply. Examiners further concluded that it was reasonable for consumers to believe that the advertised terms applied to a class of vehicles similar to the cars pictured in the ads. These representations were material as information about the central characteristics of a product or service—such as costs, benefits, and/or restrictions on the use or availability—are presumed to be material. Here, the promotional offers advertised were significantly more restricted than a consumer may have realized. In response to these findings, the institutions have stopped using the deceptive advertisements and have enhanced monitoring of marketing materials and advertisements across all product lines.

2.2 Auto Servicing

Examiners identified three unfair or abusive acts or practices at auto servicers related to charging interest on inflated loan balances, cancelling automatic payments without sufficient notice, and collection practices after repossession.

2.2.1 Collecting Interest on Fraudulent Loan Charges

When supervised institutions purchase retail installment contracts from auto dealers, dealers generally provide a document listing the options included on the vehicle. Some dealers fraudulently included in the document options that are not actually present on the vehicle, for example by listing undercoating that the vehicle does not actually have. This artificially inflates the value of the collateral, which may make it easier for the dealer to find funding for the contract from indirect lenders.

Examiners found that servicers engaged in unfair and abusive acts or practices by collecting and retaining interest borrowers paid on automobile loans that included options that were not in fact included in the collateral, leading to improperly inflated loan amounts. Examiners found that after initial loan processing, servicers attempted to contact consumers to verify that options listed by the dealer are in fact on the vehicle; consumers rarely identified discrepancies. In the event consumers identified discrepancies, servicers reduced the amounts that they paid dealers by the amount of the missing options. But servicers did not reduce the amount that consumers owed on the loan agreements and continued to charge interest tied to financing of the nonexistent options. Similarly, after repossession servicers compared the options actually present on the vehicle to the information originally provided by the dealer and, where the options were not actually included, obtained refunds from dealers that were applied to the deficiency balances. But the servicers did not refund consumers for the interest charged on the illusory options.

The CFPA defines an unfair act or practice as an act or practice that: (1) that causes or is likely to cause substantial injury to consumers; (2) which is not reasonably avoidable by consumers; and (3) is not outweighed by countervailing benefits to consumers or to competition.[6] Examiners found that servicers engaged in unfair acts or practices when they collected interest on the nonexistent options. Examiners found that consumers suffered substantial injury when they paid excess interest resulting from improperly inflated loan amounts. Consumers could not reasonably avoid the injury because they had no reason to anticipate that dealers would fraudulently include nonexistent options and that the consumers would be charged interest based on the inflated loan amount. And even if consumers attempted to validate the options included, most consumers are not able to tell—merely by sight—the options included on a car, many of which may be hidden under the hood or otherwise not readily visible. And the injury is not outweighed by countervailing benefits to consumers or competition.

Examiners also found that the servicers engaged in abusive acts or practices. An act or practice is abusive if it: (1) materially interferes with the ability of a consumer to understand a term or condition of a consumer financial product or service; or (2) takes unreasonable advantage of: a lack of understanding on the part of the consumer of the material risks, costs, or conditions of the product or service; the inability of the consumer to protect the interest of the consumer in selecting or using a consumer financial product or service; or the reasonable reliance by the consumer on a covered person to act in the best interest of the consumer.[7]

Here examiners concluded that the servicers' practices were abusive because they took unreasonable advantage of consumers' inability to protect their interests in the selection or use of the product by charging interest on loan balances that were improperly inflated because of the illusory options, which benefited the servicer to the detriment of consumers. Servicers were aware that some percentage of their loans had inflated balances and nevertheless collected excess interest on these amounts while seeking and obtaining refunds on the missing options. At the time of loan funding, consumers were unable to protect their own interests; it was impractical for them to challenge the practice because they did not know that certain options were missing.[8] After repossession, servicers continued to take advantage of consumers' inability to protect their interests where they protected themselves by obtaining refunds from dealers for the value of options the collateral vehicles did not actually have but did not refund the excess interest amounts consumers had paid based on these inflated loan balances.

In response to these findings, Supervision directed the servicers to cease the practice.

2.2.2 Canceling Automatic Payments Without Sufficient Notice

Examiners found that servicers engaged in unfair acts or practices by suspending recurring automated

[4] 12 U.S.C. 5531, 5536.

[5] *Consumer Financial Protection Bureau* v. *Gordon,* 819 F.3d 1179, 1192 (9th Cir. 2016).

[6] 12 U.S.C. 5531, 5536.

[7] 12 U.S.C. 5531(d)(2)(B).

[8] CFPB Policy Statement on Abusive Acts or Practices, at 14, *available at https://www.consumerfinance.gov/compliance/supervisory-guidance/policy-statement-on-abusiveness/* (explaining that ''inability'' includes situations where it is ''impractical'' for consumers to protect their interests).

clearing house (ACH) payments prior to consumers' final payment without sufficiently notifying consumers that the final payment must be made manually. Consumers could enroll in automatic payments by completing a written electronic funds transfer authorization. The authorizations contained a small print disclosure that servicers would not automatically withdraw the final payment; servicers did not provide any additional communication to consumers before the final payment was required. Many consumers enrolled in these automatic payments for a period of years and relied on the automatic payments. But servicers cancelled the final withdrawal and did not debit the final payment, resulting in missed payments and late fee assessment by servicers. Consumers suffered substantial injury when servicers failed to provide adequate notice that they would not debit the final payment, including the late fees servicers charged consumers when consumers missed these payments. Consumers could not reasonably avoid this injury because they believed their payments would be processed automatically and the only disclosure that the payment would be cancelled was written in fine print in the initial enrollment paperwork. And the injury is not outweighed by countervailing benefits to consumers or competition.

In response to these findings, servicers remediated consumers and revised their policies and procedures.

2.2.3 Requiring Consumers To Pay Other Debts To Redeem Vehicles

Some vehicle financing contracts contain clauses allowing servicers to use the vehicle to secure other unrelated unsecured debts consumers owe to the company, such as credit card debt; this is referred to as cross-collateralization. Examiners found that after servicers repossessed vehicles, they accelerated the amount due on the vehicle finance contract and also accelerated any other amounts the consumer owed to the entity. When consumers called to recover the vehicles, the servicers required consumers to pay the full amount on all accelerated debts, which included both debt for the vehicle and other debts.

Examiners found that servicers engaged in unfair and abusive acts or practices by engaging in the blanket practice of cross-collateralizing loans and requiring consumers to pay other debts to redeem their repossessed vehicles.

Accelerating and demanding repayment on other debts before returning repossessed vehicles was unfair. It caused substantial injury to consumers because consumers were required to pay accelerated and cross-collateralized amounts across multiple loans or lose their vehicles. Consumers could not reasonably avoid the harm caused by this practice. While servicers occasionally allowed consumers to pay lesser amounts, they did so only if consumers objected or argued about the debt and consumers were not meaningfully made aware that arguing about the cross-collateralization could result in a lesser payment amount. And even if the consumer objected, representatives still used the cross-collateral provisions as a coercive collection tactic. A blanket practice of cross-collateralizing and demanding repayment does not benefit consumers and the harm outweighs any countervailing benefits to consumers or competition.

This practice was abusive because it also took unreasonable advantage of a lack of understanding of consumers of the material risks, costs, or conditions of their loan agreements. When consumers sought to reinstate their loans after repossession, servicers utilized contractual remedies to accelerate all debts owed to them which resulted in a significant monetary advantage to servicers while imposing a corresponding degree of economic harm on the consumer. These practices also inflicted significant emotional and psychological distress. The advantage gained by the servicers was unreasonable in the ordinary case of vehicle repossession. And consumers lacked an understanding of the material risks, costs, or conditions of the specific contractual remedies allowing for cross-collateralization at issue in the relevant loans.[9]

In response to these findings, servicers remediated consumers and revised policies and procedures.

2.3 Consumer Reporting

Companies that regularly assemble or evaluate information about consumers for the purpose of providing consumer reports to third parties are ''consumer reporting companies'' (CRCs).[10] These companies, along with the entities—such as banks, loan servicers, and others—that furnish information to the CRCs for inclusion in consumer reports, play a vital role in the availability of credit and have a significant role to play in the fair and accurate reporting of credit information. They are subject to several requirements under the Fair Credit Reporting Act (FCRA)[11] and its implementing regulation, Regulation V,[12] including the requirement to reasonably investigate disputes and to furnish data subject to the relevant accuracy requirements. In recent reviews, examiners found deficiencies in CRCs' compliance with FCRA permissible purpose-related policy and procedure requirements and furnisher compliance with FCRA and Regulation V dispute investigation requirements.

2.3.1 CRC Duty To Maintain Reasonable Policies and Procedures Designed To Limit Furnishing Consumer Reports to Persons With Permissible Purpose(s)

The FCRA requires that CRCs must maintain reasonable procedures designed to limit the furnishing of consumer reports to persons with at least one of the permissible purposes enumerated under section 604(a) of the FCRA.[13] In recent reviews of CRCs, examiners found that CRCs' procedures relating to ensuring end users of consumer reports have a requisite permissible purpose failed to comply with this obligation because the CRCs' procedures posed an unreasonable risk of improperly disclosing consumer reports to persons without a permissible purpose. For example, examiners identified multiple deficiencies in the CRCs' procedures, such as failing to maintain an adequate process for re-assessing end users' permissible purpose(s) where indicia of improper consumer report use by an end user is present. This created heightened risk of improper consumer report disclosures. In some instances, examiners found that such deficiencies resulted in CRCs furnishing consumer reports to end users despite having reasonable grounds to believe the end users did not have a requisite permissible purpose.

In response to these findings, CRCs are revising policies and procedures for, and their oversight of, onboarding end users and periodically re-assessing end users' permissible purpose(s). CRCs also are revising processes relating to the monitoring of end users, including the identification of end users exhibiting

[9] *See* CFPB Policy Statement on Abusive Acts or Practices, at 12, *available at https://www.consumerfinance.gov/compliance/supervisory-guidance/policy-statement-on-abusiveness/* (explaining that ''risks'' includes the consequence of default).

[10] The term ''consumer reporting company'' means the same as ''consumer reporting agency,'' as defined in the Fair Credit Reporting Act, 15 U.S.C. 1681a(f), including nationwide consumer reporting agencies as defined in 15 U.S.C. 1681a(p) and nationwide specialty consumer reporting agencies as defined in 15 U.S.C. 1681a(x).

[11] 15 U.S.C. 1681 *et seq.*

[12] 12 CFR part 1022.

[13] 15 U.S.C. 1681e(a).

indicia of impermissible consumer report use.

2.3.2 Furnisher Duty To Review Policies and Procedures and Update Them as Necessary To Ensure Their Continued Effectiveness

Examiners found that furnishers are violating the Regulation V duty to periodically review their policies and procedures concerning the accuracy and integrity of furnished information and update them as necessary to ensure their continued effectiveness.[14] Specifically, in recent reviews of auto furnishers, examiners found that furnishers failed to review and update policies and procedures after implementing substantial changes to their dispute handling processes. For example, furnishers changed software systems for use in the investigation of disputes but maintained policies and procedures that referenced only systems no longer in use, inhibiting the continued effectiveness of those policies and procedures. In response to these findings, furnishers are updating their policies and procedures to reflect current systems and training staff to use them in handling disputes.

2.3.3 Furnisher Duty To Conduct Reasonable Investigations of Direct Disputes

Examiners are continuing to find that furnishers are violating the Regulation V duty to conduct a reasonable investigation of direct disputes.[15] In recent reviews of mortgage furnishers, examiners found the furnishers failed to conduct any investigations of direct disputes that were received at an address provided by the furnishers to CRCs and set forth on consumer reports. Rather than investigate direct disputes sent to these qualifying addresses under Regulation V, the furnishers responded to the disputes by instructing the consumers to re-send their direct disputes to certain other addresses of the furnishers and only investigated the disputes to the extent the consumers re-sent them per these instructions. In response to these findings, furnishers are updating their policies and procedures to ensure that they conduct reasonable investigations of direct disputes that are sent to addresses provided by the furnishers to CRCs and set forth on consumer reports.

2.3.4 Furnisher Duty To Notify Consumers That a Dispute Is Frivolous or Irrelevant

Examiners are continuing to find that furnishers are violating the Regulation V duty to provide consumers with notices regarding frivolous or irrelevant disputes.[16] In recent reviews of third-party debt collector furnishers, examiners found that furnishers failed to send any notice to consumers whose direct disputes they determined were frivolous or irrelevant. For example, when furnishers determined that disputes sent by consumers were duplicative of prior disputes, the furnishers did not investigate the disputes nor send notices to consumers setting forth the reasons for their determination and the information the consumers needed to submit for the furnishers to investigate the disputed information. In response to these findings, furnishers are establishing policies and procedures to identify and respond to frivolous or irrelevant disputes, including sending a letter to the consumer notifying the consumer of the determination that a dispute is frivolous or irrelevant and identifying the additional information needed to investigate the consumer's dispute.

2.3.5 Furnisher Duty To Inform Consumers of Information Needed To Investigate Frivolous or Irrelevant Disputes

Examiners are continuing to find that furnishers are violating their Regulation V duty, after making a determination that a direct dispute is frivolous or irrelevant, to include in their notices to consumers the reasons for that determination and to identify any information required to investigate the disputed information.[17] In recent reviews of mortgage furnishers, examiners found that furnishers sent frivolous or irrelevant notices to consumers that failed to accurately convey what information the consumers needed to submit for the furnishers to investigate the disputed information. For example, furnishers sent consumers a frivolous notification stating that consumers must provide their entire unredacted credit report for the furnishers to investigate the dispute, even though an entire unredacted credit report was not required for the investigation and an excerpt of the relevant portion of the credit report would have sufficed. In response to these findings, furnishers are updating the content of their frivolous or irrelevant notices to eliminate the language requesting an entire unredacted credit report as a prerequisite for investigation.

2.3.6 Furnishers' Failure To Provide Adequate Address-Disclosures for Notices

Section 623(a)(1)(A) of the FCRA requires that a furnisher must not furnish to any CRC any information relating to a consumer if the furnisher knows or has reasonable cause to believe that the information is inaccurate.[18] A furnisher is not subject to section 623(a)(1)(A) if the furnisher clearly and conspicuously specifies to consumers an address at which consumers may notify the furnisher that information it furnished is inaccurate.[19] The FCRA does not require a furnisher to specify such an address. If a furnisher clearly and conspicuously specifies such an address, it is not subject to section 623(a)(1)(A) but must comply with section 623(a)(1)(B) of the FCRA, which provides that a furnisher shall not furnish information relating to a consumer to a CRC if it has been notified by the consumer, at the address specified for such notices, that certain information is inaccurate and such information is, in fact, inaccurate.[20] A furnisher that specifies an address may also be subject to section 623(a)(2) of the FCRA if it determines that information it has furnished is not complete or accurate and fails to notify the CRC and provide corrections.[21]

Examiners are continuing to find that furnishers are not clearly and conspicuously specifying to consumers an address for notices at which a consumer may notify the furnisher that information is inaccurate. In reviews of third-party debt collection furnishers, examiners found that the only notice or dispute address furnishers provided to consumers was an address included on debt validation notices for the purpose of disputing the validity of a debt. Examiners found that the debt validation notices did not specify to consumers an address for, or otherwise specify that the debt validity dispute address may also be used for, notices relating to inaccurately furnished consumer report information. As a result, examiners found that the furnishers have not met the requirement in section 623(a)(1)(C) of the FCRA to not be subject to section 623(a)(1)(A) and therefore are subject to the stricter

[14] 12 CFR 1022.42(c).

[15] 12 CFR 1022.43(e).

[16] 12 CFR 1022.43(f)(2).

[17] 12 CFR 1022.43(f)(3).

[18] 15 U.S.C. 1681s–2(a)(1)(A).

[19] 15 U.S.C. 1681s–2(a)(1)(C).

[20] *Id.* (cross-referencing 15 U.S.C. 1681s–2(a)(1)(B)).

[21] 15 U.S.C. 1681s–2(a)(2).

prohibition under section 623(a)(1)(A) of the FCRA against furnishing information the furnishers know or have reasonable cause to believe is inaccurate.

2.4 Debt Collection

The CFPB has supervisory authority to examine certain institutions that engage in consumer debt collection activities, including very large depository institutions, nonbanks that are larger participants in the consumer debt collection market, and nonbanks that are service providers to certain covered persons. Recent examinations of larger participant debt collectors identified violations of the Fair Debt Collection Practices Act (FDCPA) as well as the CFPA.

2.4.1 Unlawful Attempts To Collect Medical Debt

Examiners found that debt collectors continued collection attempts for work-related medical debt after receiving sufficient information to render the debt uncollectible under State worker's compensation law absent written evidence to the contrary, which the collector did not obtain from its client. The collectors made multiple calls over several years, during which they implied that the consumer owed the debt and asserted that the ambulance ride that gave rise to the debt originated from the consumer's home, despite evidence in their files that it originated from the consumer's workplace. Examiners found that, through these practices, the debt collectors violated the FDCPA by collecting an amount not permitted by law or agreement,[22] by falsely representing the character, amount, or legal status of a debt,[23] by engaging in conduct which had the natural consequence of harassing, oppressing, or abusing the consumer,[24] and by using false, deceptive, or misleading representations in connection with the collection of a debt.[25]

In response to these findings, Supervision directed the debt collectors to establish and maintain adequate collection policies, procedures, and training to include specific limitations on circumstances under which the collectors may contact consumers in connection with pending workers' compensation claims; enhancing call monitoring to include a review of accounts with a pending workers' compensation claim; and ensuring accounts are monitored for pending workers' compensation claims and collection attempts on such accounts are ceased.

2.4.2 Deceptive Representations About Interest Payments

Examiners found that debt collectors advised consumers that if they paid the balance in full by a date certain, any interest assessed on the debt would be reversed. The debt collectors then failed to credit the consumers' accounts with the accrued additional interest, resulting in the consumers paying more than the agreed upon amount. Examiners found this practice to be deceptive in violation of the CFPA.[26] In response to these findings, Supervision directed the debt collectors to remediate all consumers who had overpaid.

2.5 Deposits

The CFPB continues to examine financial institutions to assess whether they have engaged in UDAAPs prohibited by the CFPA.[27] The CFPB also continues its examinations of supervised institutions for compliance with Regulation E,[28] which implements the Electronic Fund Transfer Act (EFTA).[29] The CFPB also examines for compliance with other relevant statutes and regulations, including Regulation DD,[30] which implements the Truth in Savings Act.[31]

2.5.1 Unfair Line of Credit Usage and Fees

The CFPA prohibits any ''covered person'' from ''engag[ing] in any unfair, deceptive, or abusive act or practice.'' [32]

Examiners found unfair acts or practices due to institutions' assessment of both nonsufficient funds (NSF) and line of credit transfer fees on the same transaction. The institutions offered a line of credit program that consumers could opt-in to. If a consumer's checking account did not have sufficient funds to pay for a transaction, the institutions would transfer funds from the line of credit to cover the transaction and assess a line of credit transfer fee, as well as interest on the amount of credit extended. In some instances, the line of credit might not have sufficient funds to cover the transaction, in which case the institutions would deny the transaction and assess an NSF fee on the denied transaction. As the transaction was declined, no funds from the line of credit would be transferred to pay the transaction. But, if there were insufficient funds in the consumer's checking account to pay the NSF fee and that NSF fee overdrew the consumer's account, the institutions would automatically transfer funds from the line of credit to the consumer's checking account and assess a line of credit transfer fee.

Supervision found the institutions' practice of assessing both the NSF and the line of credit transfer fee on the same transaction is an unfair act or practice. These acts or practices caused or were likely to cause substantial injury in the form of two fees being assessed on the same denied transaction. Consumers who enrolled in the line of credit program were charged two fees instead of the single fee charged to those who were not enrolled, even though in both cases the transaction was returned unpaid. A consumer could not reasonably avoid this substantial injury as the consumer had no notice of the potential for double fees or ability to avoid the double fees in this automated process and would not reasonably expect that enrolling in a program meant to prevent overdraft and decrease fees related to denied transactions would instead increase them. These acts or practices did not provide benefits to consumers or competition.

The supervised institutions believed they had safeguards in place to not assess NSF fees and line of credit fees on the same transaction. Specifically, they programmed their systems to not assess both of these fees on the same day. The way the institutions' systems posted NSF fees, however, meant that the NSF and line of credit fees were incurred on different days, even though they were part of the same transaction. Thus, the safeguard was inadequate. In response to these findings, the institutions committed to system changes and remediated $113,358 to 4,147 consumers. The system change implemented by the supervised institutions was to avoid the issue altogether by entirely eliminating NSF fees for unpaid transactions.

2.6 Fair Lending

The CFPB's fair lending supervision program assesses compliance with the Equal Credit Opportunity Act (ECOA) [33] and its implementing regulation, Regulation B,[34] as well as the Home Mortgage Disclosure Act (HMDA) [35] and its implementing regulation, Regulation

[22] 15 U.S.C. 1692f(1).
[23] 15 U.S.C. 1692e(2)(A).
[24] 15 U.S.C. 1692d.
[25] 15 U.S.C. 1692e.
[26] 12 U.S.C. 5536(a)(1)(B).
[27] 12 U.S.C. 5531, 5536.
[28] 12 CFR 1005 *et seq.*
[29] 15 U.S.C. 1693 *et seq.*
[30] 12 CFR 1030 *et seq.*
[31] 12 U.S.C. 4301 *et seq.*
[32] 12 U.S.C. 5536.
[33] 15 U.S.C. 1691–1691*f.*
[34] 12 CFR pt. 1002.
[35] 12 U.S.C. 2801–2810.

C,[36] at institutions subject to the CFPB's supervisory authority. ECOA prohibits a creditor from discriminating against any applicant, with respect to any aspect of a credit transaction, on the basis of race, sex, color, religion, national origin, sex (including sexual orientation and gender identity), marital status, or age (provided the applicant has the capacity to contract), because all or part of the applicant's income derives from any public assistance program, or because the applicant has in good faith exercised any right under the Consumer Credit Protection Act.[37]

During recent examinations, Examiners found lenders violated ECOA and Regulation B.

2.6.1 Pricing Discrimination

In the Fall 2021 issue of *Supervisory Highlights,* the CFPB discussed findings that mortgage lenders violated ECOA and Regulation B by discriminating against African American and female borrowers in the granting of pricing exceptions based upon competitive offers from other institutions.[38] Since then, Supervision conducted additional examinations assessing mortgage lenders' compliance with ECOA and Regulation B with respect to the granting of pricing exceptions based on competitive offers from other institutions. The CFPB again found that mortgage lenders violated ECOA and Regulation B by discriminating in the incidence of granting pricing exceptions across a range of ECOA-protected characteristics, including race, national origin, sex, or age.

Examiners observed that certain lenders maintained policies and procedures that permitted the granting of pricing exceptions to consumers, including pricing exceptions for competitive offers. Generally, a pricing exception is when a lender makes exceptions to its established credit standards. For example, a lender may lower a rate to match a competitor's offer and retain the consumer. Examiners identified lenders with statistically significant disparities for the incidence of pricing exceptions at differential rates on a prohibited basis compared to similarly situated borrowers. Weaknesses in the lenders' policies and procedures with respect to pricing exceptions for competitive offers, the failure of mortgage loan officers to follow those policies and procedures, the lenders' lack of oversight and control over their mortgage loan officers' discretion in connection with and use of such exceptions, or managements' failure to take appropriate corrective action risks contributed to the observed disparities in the incidence of granting pricing exceptions. Examiners did not identify evidence of legitimate, non-discriminatory reasons that explained the disparities observed in the statistical analysis.

In several instances, examiners identified policies and procedures that were not designed to effectively mitigate ECOA and Regulation B violations or manage associated risks of harm to consumers. Some policies permitted mortgage loan officers to request a pricing exception by submitting a request into the loan origination system without requiring that the request be substantiated by documentation. While those requests were subject to managerial review, there were no guidelines for the bases for approval or denial of the exception request or the amount of the exception. Other policies had limited documentation requirements—and sometimes no documentation requirements for pricing exceptions below a certain threshold. This meant that the lenders could not effectively monitor whether the pricing exception request was initiated by the consumer and/or supported by a competitive offer to the consumer. Other policies granted some loan officers pricing exception authority up to certain thresholds without the need for competitive offer documentation or management approval. As a result, the lenders did not flag those discretionary discounts as pricing exceptions and did not monitor them. Some policies had more robust documentation and approval requirements. But those institutions did not effectively monitor interactions between loan officers and consumers to ensure that the policies were followed and that the loan officer was not coaching certain consumers and not others regarding the competitive match process. In other instances, examiners determined that loan officers were not properly documenting the initiation source of the concession request nor were they retaining and documenting competitors' pricing information in borrowers' files as required by the lender policy.

Examiners also identified weaknesses in training programs. Some lenders did not have training that explicitly addressed fair lending risks associated with pricing exceptions, including the risks of providing different levels of assistance to customers, on prohibited bases, in connection with a customer's request for a price exception. Other training programs did not cover pricing exceptions risk for employees who have discretionary pricing authority.

Finally, examiners concluded that management and board oversight at lenders was not sufficient to identify and address risk of harm to consumers from the lender's pricing exceptions practices. Similarly, examiners observed that some lenders failed to take corrective action based on their statistical observations of disparities in pricing exceptions. Some lenders failed to document whether additional investigation into observed disparities was warranted, review the causes of such disparities, or consider actions that might reduce such disparities.

In response to these findings, the CFPB directed lenders to, among other things: enhance or implement pricing exception policies and procedures to mitigate fair lending risks, including enhancing documentation standards and requiring clear exception criteria; enhance or implement policies requiring the retention of documentation for all pricing exceptions, including document regarding whether the pricing exception request was initiated by the consumer; develop and implement a monitoring and audit program to effectively identify and mitigate potential disparities and/or fair lending risks associated with the pricing exception approval process; or to identify and remediate harmed consumers.

2.6.2 Discriminatory Lending Restrictions

The CFPB recently reviewed lending restrictions in underwriting policies and procedures at several lenders to evaluate fair lending risks and to assess compliance with ECOA and Regulation B. The reviews focused on lending restrictions relating to how those lenders handled the treatment of applicants' criminal records and whether the lenders properly treated income derived from public assistance.

Regarding prior contact with the criminal justice system, both national data and the history of discrimination in the justice system suggest that restrictions on lending based on criminal history are, in many circumstances, likely to have a disparate impact based on race and national origin.[39] Thus, the use of criminal history in credit decisioning may create a heightened risk of violating ECOA and Regulation B. The CFPB's review

[36] 12 CFR pt. 1003.

[37] 15 U.S.C. 1691(a).

[38] *Supervisory Highlights,* Issue 25, Fall 2021, sec. 2.4.1.

[39] CFPB, Justice-Involved Individuals and the Consumer Financial Marketplace (Jan. 2022), *available at https://files.consumerfinance.gov/f/documents/cfpb_jic_report_2022-01.pdf.*

identified risky policies and procedures at several institutions for several areas of credit, including mortgage origination, auto lending, and credit cards, but most notably within small business lending. A common thread in the CFPB review was that the discovery of criminal records prompted enhanced or second-level underwriting review. However, policies and procedures at several institutions did not provide detail regarding how that review should be conducted, creating fair lending risk around how the reviewing official exercises discretion. There were variations amongst the policies and procedures as to how the lender identified criminal records and which violations or charges triggered further review or denial. For example, some lenders generally denied credit when it identified applicants with felony convictions for financial crimes but did not deny credit for arrests or non-felony convictions. Other lenders treated criminal indictments, fraud cases, sexual offenses, and industry bans as significant risks. But without clear guidelines and well-defined standards designed to meet legitimate business needs, lenders risked violating ECOA and Regulation B by applying these underwriting restrictions in a manner that could discriminate on a prohibited basis.

With respect to the proper treatment of public assistance income in underwriting, ECOA and Regulation B prohibit discrimination against applicants, with respect to any aspect of a credit transaction, because all or part of the applicant's income derives from any public assistance program.[40] Examiners identified lenders whose policies and procedures excluded income derived from certain public assistance programs or imposed stricter standards on income derived from public assistance programs. Lenders maintained a written policy that expressly prohibited underwriters from considering Home Assistance Payments provided by the Section 8 Housing Choice Voucher Homeownership Program.[41] Lenders participated in mortgage lending programs that provided consumers with a benefit in the form of a mortgage credit certificate but did not treat those benefits as income under their underwriting standards. Some lenders maintained a policy with a six-year continuity-of-income requirement for applicants relying primarily on public assistance income that was stricter than the three-year requirements applicable to other applicants' income.

In response to these findings, the CFPB directed lenders to review, identify, and provide relief to any applicant negatively affected by these policies. Lenders were also directed to revise and implement policies and procedures and enhance related systems to ensure public assistance income is evaluated under standards applicable to other sources of income.

2.7 Information Technology

The CFPB's Supervision program evaluates information technology controls at supervised institutions that may impact compliance with Federal consumer financial law or implicate risk to consumers. The CFPB assesses the effectiveness of information technology controls in detecting and preventing data breaches and cyberattacks. For example, inadequate security for sensitive consumer information, weak password management controls, untimely software updates or failing to implement multi-factor authentication or a reasonable equivalent could cause or contribute to violations of law including the prohibition against engaging in UDAAPs.[42]

Examiners found that institutions engaged in unfair acts or practices prohibited by the CFPA by failing to implement adequate information technology controls.

2.7.1 Failing To Implement Adequate Information Technology Security Controls

Examiners found that institutions engaged in unfair acts or practices by failing to implement adequate information technology security controls that could have prevented or mitigated cyberattacks. More specifically, the institutions' password management policies for certain online accounts were weak, the entities failed to establish adequate controls in connection with log-in attempts, and the same entities also did not adequately implement multi-factor authentication or a reasonable equivalent for consumer accounts.

The entities' lack of adequate information technology security controls caused substantial harm to consumers when bad actors accessed almost 8,000 consumer bank accounts and made fraudulent withdrawals in the sum of at least $800,000. Consumers were also injured because they had to devote significant time and resources to dealing with the impacts of the incident. For example, consumers had to contact the institutions to file disputes to determine why funds were missing from their accounts and then wait to be reimbursed by the institutions. Consumers may have had to spend additional time enrolling in credit monitoring services, identity theft protection services or changing their log-in credentials.

The impacted consumers could not reasonably avoid the injury caused by the institutions' inadequate information technology security controls. Consumers do not have control over certain aspects of an institutions' security features, such as how many log-in attempts an institution allows before locking an account or the number of transactions it labels suspicious, requiring additional verification. Similarly, only the institutions can implement measures to mitigate or prevent cyberattacks such as employing controls or tools to block automated malicious software (botnet) activity or ensuring sufficient authentication protocols are in place such as multi-factor authentication or an alternative of equivalent strength. Consumers do not have control over these security measures and were unable to reasonably avoid the injury caused by the cyberattacks. The injury to consumers outweighs any countervailing benefits, such as avoiding the cost of implementing information technology controls necessary to prevent these types of attacks.

In response to these findings, the institutions are implementing multi-factor authentication, or a reasonable equivalent, enhancing password management practices and implementing adequate controls for failed log-in attempts to prevent/mitigate unauthorized access to consumer accounts. Additionally, the institutions are providing remediation to impacted consumers.

2.8 Mortgage Origination

The CFPB assessed mortgage origination operations of several supervised institutions for compliance with applicable Federal consumer financial laws including Regulation Z.

[40] 15 U.S.C. 1691(a)(3); 12 CFR 1002.4(a).

[41] In 2015, the CFPB issued a compliance bulletin reminding creditors of their obligations under ECOA and Regulation B to provide non-discriminatory access to credit for mortgage applicants using income from the Section 8 Housing Choice Voucher Homeownership Program. CFPB Bulletin 2015–01, Section 8 Housing Choice Voucher Homeownership Program, *available at https://files.consumerfinance.gov/f/201505_cfpb_bulletin-section-8-housing-choice-voucher-homeownership-program.pdf.*

[42] These deficiencies may also violate other Federal laws governing data security for financial institutions such as the Safeguards Rules issued under the Gramm-Leach-Bliley Act.

2.8.1 Loan Originator Compensation: Differentiations Based on Product Type

Regulation Z generally prohibits compensating mortgage loan originators in an amount that is based on the terms of a transaction.[43] It defines a term of a transaction as ''any right or obligation of the parties to a credit transaction.'' [44] And it provides that a determination of whether compensation is ''based on'' a term of a transaction is made based on objective facts and circumstances indicating that compensation would have been different if a transaction term had been different.[45] Accordingly, in the preamble to the CFPB's 2013 Loan Originator Final Rule, the CFPB clarified that it is ''not permissible to differentiate compensation based on credit product type, since products are simply a bundle of particular terms.'' [46]

As part of their business model, institutions brokered-out certain mortgage products not offered in-house. For example, the institutions used outside lenders for reverse mortgage originations, but had their own in-house cash-out refinance mortgage product. Examiners determined that the institutions used a compensation plan that allowed a loan originator who originated both brokered-out and in-house loans to receive a different level of compensation for the brokered-out loans versus in-house loans. By compensating differently for loan product types that were not offered in-house, the entities violated Regulation Z by basing compensation on the terms of a transaction. In response to these findings, the entities have since revised their loan originator compensation plans to comply with Regulation Z.

2.8.2 Loan Disclosures: Failure To Reflect the Terms of the Legal Obligation on Disclosures

Regulation Z requires that disclosures ''shall reflect the terms of the legal obligation between the parties.'' [47] In most cases, disclosures should reflect the terms to which both the consumer and creditor are legally bound at the outset of a transaction.[48]

Examiners found that the standard adjustable-rate promissory note used by an institution stated that the result of the margin plus the current index should be rounded up or down to the nearest one-eighth of one percentage point. However, examiners discovered that the institutions' loan origination system was not programmed to round. Thus, the fully indexed rate that the entity calculated and provided on their disclosures was calculated contrary to the promissory note for the loan. Consequently, the supervised institutions failed to reflect the terms of the legal obligation on disclosures in violation of Regulation Z.[49] In response to these findings, the supervised institutions reconfigured their loan origination system to round according to the promissory note.

2.9 Mortgage Servicing

Examiners identified UDAAP and regulatory violations at mortgage servicers, including violations during the loss mitigation and servicing transfer processes, as well as payment posting violations.

2.9.1 Loss Mitigation Timing Violations

If a servicer receives a complete application more than 37 days before a scheduled foreclosure sale, then Regulation X [50] requires servicers to evaluate the complete loss mitigation applications within 30 days of receipt and provide written notices to borrowers stating which loss mitigation options, if any, are available. Examiners found that some servicers violated Regulation X when they failed to evaluate complete applications within 30 days of receipt.[51] Relatedly, some servicers evaluated the application within 30 days but failed to provide the required notice to borrowers within 30 days as required.[52] In response to these findings, servicers improved policies and implemented additional training.

Additionally, examiners found that servicers engaged in an unfair act or practice when they delayed processing borrower requests to enroll in loss mitigation options, including COVID–19 pandemic-related forbearance extensions, based on incomplete applications.[53] These delays varied in length, including delays up to six months. Borrowers were substantially injured because they suffered one or more of the following harms: prolonged delinquency, late fees, default notices, and lost time and resources addressing servicer delays. Borrowers also experienced negative credit reporting because of the servicers' delays, resulting in a risk of damage to their credit that may have materialized into financial injury. Borrowers could not reasonably avoid injury because servicers controlled the processing of applications, and borrowers reasonably expected servicers to enroll them in the options they applied for. And the injury to consumers was not outweighed by benefits to consumers or competition.

In response to these findings, servicers ceased the practice and developed improved policies and procedures.

2.9.2 Mispresenting Loss Mitigation Application Response Times

Examiners found that servicers engaged in deceptive acts or practices when they informed consumers, orally and in written notices, that they would evaluate their complete loss mitigation applications within 30 days, but then moved toward foreclosure without completing the evaluations. Because the servicers received the complete loss mitigation applications 37 days or less before foreclosure, Regulation X did not require the servicers to evaluate the application within 30 days.[54] But the servicers informed consumers in written and oral communications that they would evaluate borrowers' complete loss mitigation applications within 30 days, and these representations created the overall net impression that foreclosure would not occur until the servicers rendered decisions on the applications. The borrowers reasonably interpreted these representations to mean that they would receive decisions on the applications, and potentially a period of time to take other actions if the applications were denied, prior to foreclosure. Finally, the servicers' representations were material, as they prompted the borrowers to wait for notification concerning a possible loan modification and discouraged the borrowers from taking additional steps to prepare for foreclosure.

In response to these findings, servicers ceased the practice and

[43] 12 CFR 1026.36(d)(1)(i).

[44] 12 CFR 1026.36(d)(1)(ii).

[45] 12 CFR 1026.36(d)(1)(i), comment 36(d)(1)–1.i.

[46] 2013 Loan Originator Compensation Rule, 78 FR 11279, 11326–27, n.82 (Feb. 15, 2013).

[47] 12 CFR 1026.17(c)(1).

[48] 12 CFR 1026.17(c)(1), comment 17(c)(1)–1.

[49] 12 CFR 1026.38(o)(1)(i) and 12 CFR 1026.38(o)(2)(i).

[50] 12 CFR 1024.41(c)(1).

[51] 12 CFR 1024.41(c)(1)(i).

[52] 12 CFR 1024.41(c)(1)(ii).

[53] Generally, servicers must not evade the requirement to evaluate a complete loss mitigation application by offering a loss mitigation option based on evaluation of an incomplete application. 12 CFR 1024.41(c)(2)(i). But servicers may offer certain types of loss mitigation options based on incomplete applications, such as short-term loss mitigation options or certain loss mitigation options made available to borrowers experiencing a COVID–19-related hardship as specified by Regulation X. 12 CFR 1024.41(c)(2)(iii), (v), & (vi). When consumers apply for these options, the Regulation X requirement that servicers must evaluate applications within 30 days frequently does not apply because the consumer has not submitted a complete application. 12 CFR 1024.41(c)(1). In some instances, consumers applying for these options do submit a complete application and the Regulation X 30-day evaluation requirement does apply.

[54] 12 CFR 1024.41(c)(3)(ii)(B).

developed improved policies and procedures.

2.9.3 Assigning Continuity of Contact Personnel

Under Regulation X, servicers are required to establish continuity of contact with delinquent consumers by maintaining policies and procedures to assign personnel to delinquent borrowers by, at the latest, the 45th day of delinquency.[55] These personnel should be made available to answer delinquent borrowers' questions via telephone, and the servicer shall maintain policies and procedures that are reasonably designed to ensure these personnel can perform certain functions.[56] These include providing accurate information about loss mitigation and timely retrieving written information provided by the borrower to the servicer in connection with a loss mitigation application.[57]

Examiners found that servicers violated Regulation X by failing to maintain adequate continuity of contact procedures.[58] Servicers did not maintain policies and procedures that were reasonably designed to ensure that personnel were made available to borrowers via telephone and provided timely live responses if borrowers were unable to reach continuity of contact personnel; the servicers routinely failed to return phone calls from borrowers.[59] And when consumers did speak with personnel, the personnel failed to provide accurate information about loss mitigation options that were available.[60] Additionally, servicers' systems did not allow the assigned personnel to retrieve, in a timely manner, written information that the consumer had already provided in connection with their loss mitigation applications, causing assigned personnel to ask for information already in the servicers' possession.[61]

In response to these findings, servicers updated their servicing platforms, developed new monitoring reports, implemented additional trainings, and revised policies and procedures.

2.9.4 Spanish Language Acknowledgement Notices Missing Information

Regulation X requires servicers, in most circumstances, to provide borrowers with a written acknowledgment notice within 5 days of receipt of a loss mitigation application.[62] This notice must contain a statement that the borrower should consider contacting servicers of any other mortgage secured by the same property to discuss loss mitigation options.[63] Examiners found that servicers violated Regulation X by failing to include this required language on Spanish language application acknowledgment notices. In contrast, servicers included this language on English language acknowledgment notices sent to English speaking consumers. In response to these findings, servicers updated their letter templates.

2.9.5 Failure To Provide Critical Loss Mitigation Information

Examiners found that servicers violated Regulation X and Regulation Z by failing to provide specific required information in several circumstances:

- Specific reasons for denial when they sent notices that included vague denial reasons, such as informing consumers that they did not meet the eligibility requirements for the program;[64]
- Correct payment and duration information for forbearance;[65] and
- Information in periodic statements about loss mitigation programs, such as forbearance, to which consumers had agreed.[66]

In response to these findings, servicers updated their letter templates and enhanced monitoring.

2.9.6 Failure To Credit Payment Sent to Prior Servicer After Transfer

After a transfer of servicing, Regulation X requires that, during the 60-day period beginning on the effective date of transfer, servicers not treat payments sent to the transferor servicer as late if the transferor servicer receives them on or before the due date.[67] Examiners found that servicers treated payments received by the transferor servicer during the 60-day period, but not transmitted by the transferor to the transferee until after the 60-day period, as late. This violated Regulation X because the transferor had received the payment within the 60-day period beginning on the effective date of the transfer. In response to these findings servicers remediated consumers and updated policies, procedures, training, and internal controls.

2.9.7 Failure To Maintain Policies and Procedures Reasonably Designed To Identify Missing Information After a Transfer

Regulation X[68] requires servicers to maintain policies and procedures that are reasonably designed to achieve the objectives in 12 CFR 1024.38(b). Commentary to Regulation X clarifies that ''procedures'' refers to the actual practices followed by the servicer.[69] Under Regulation X,[70] transferee servicers are required to maintain policies and procedures to identify necessary documents and information that may not have been included in a servicing transfer and obtain such information from the transferor servicer.

Examiners found that some servicers violated Regulation X when they failed to maintain policies and procedures reasonably designed to achieve the objective of facilitating transfer of information during servicing transfers. For example, servicers' policies and procedures were not reasonably designed because they failed to obtain copies of the security instruments, or any documents reestablishing the security instrument, to establish the lien securing the mortgage loans after servicing transfers. In response to these findings, servicers updated their policies and procedures and implemented new training.

2.10 Payday and Small-Dollar Lending

During examinations of payday and small-dollar lenders, Supervision identified unfair, deceptive, and abusive acts or practices and violations of Regulation Z. Supervision also identified risks associated with the Military Lending Act.

2.10.1 Unreasonable Limitations on Collection Communications

Examiners found that lenders engaged in abusive and deceptive acts or practices in connection with short-term, small-dollar loans, by including language in loan agreements purporting

[55] 12 CFR 1024.40(a).

[56] 12 CFR 1024.40(a)(2); 12 CFR 1024.40(b).

[57] 12 CFR 1024.40(b)(1) and (2).

[58] 12 CFR 1024.40(a) and (b).

[59] 12 CFR 1024.40(a)(2) and (3).

[60] 12 CFR 1024.40(b)(1).

[61] 12 CFR 1024.40(b)(2)(ii).

[62] 12 CFR 1024.41(b)(2)(i)(B).

[63] 12 CFR 1024.41(b)(2)(i)(B).

[64] If a servicer denies a borrower's complete loss mitigation application for any loan modification option available to the borrower, then its evaluation notice required by 12 CFR 1024.41(c)(1)(ii) must include the specific reason or reasons for the denial. 12 CFR 1024.41(d).

[65] When a servicer offers a short-term loss mitigation option, such as a forbearance plan, it must promptly provide a written notice that includes the specific payment terms and duration of the program. 12 CFR 1024.41(c)(2)(iii).

[66] Regulation Z requires servicers to include delinquency information on the periodic statement, or in a separate letter, if a consumer is more than 45 days delinquent. 12 CFR 1026.41(d)(8). This includes a requirement to provide a notice of any loss mitigation program to which the consumer has agreed. 12 CFR 1026.41(d)(8)(iv).

[67] 12 CFR 1024.33(c)(1).

[68] 12 CFR 1024.38(a).

[69] 12 CFR 1024.38(a)—comment 2.

[70] 12 CFR 1024.38(b)(4)(ii).

to prohibit consumers from revoking their consent for the lender to call, text, or email the consumers. The agreements stated, for example, that consumers, ''cannot revoke this consent to call, text, or email about your existing loan'' and that ''[n]one of our employees are authorized to receive a verbal revocation of this authorization.'' Lenders that engage in unreasonable collections communications may violate the CFPA's prohibition against UDAAP. By implying that consumers could not take action to limit unreasonable collections communications, this practice was abusive because it took unreasonable advantage of the consumers' inabilities to protect their interests in selecting or using a consumer financial product or service by limiting such collections communications. The practice was also deceptive because it misled or was likely to mislead consumers acting reasonably as to a material fact, *i.e.,* whether or not they could protect themselves by limiting unreasonable communications by phone, text, or email, and whether the lenders had an obligation to honor such requests. The practice was further abusive and deceptive under the above analyses because, contrary to the language of the loan agreements, the lenders' procedures did in fact require the lenders' representatives to allow consumers to revoke consent to communications.

In response to these findings, Supervision directed the lenders to revise the contract language to cease misleading consumers about their ability to limit collections calls, texts, and emails to reasonable channels, locations, and times, and to cease taking unreasonable advantage of consumers' inabilities to protect themselves against unreasonable or unlawful collection communications.

2.10.2 False Collection Threats

Examiners found that supervised institutions made false collection threats related to litigation, garnishment, and late fees, each of which constituted deceptive acts or practices in violation of the CFPA. The lenders sent letters to delinquent payday loan borrowers in certain states, stating that the supervised institutions ''may pursue any legal remedies available to us'' unless the consumer contacted the institution to discuss the delinquency. The representations misled or were likely to mislead borrowers into reasonably believing that the supervised institutions might take legal action against the consumer to collect the debt if the consumer did not make timely payment. It would be reasonable for consumers to interpret a threat to pursue ''any legal remedies available to us'' to include the legal remedy of a lawsuit or other similar civil action. The supervised institutions, however, never pursued such legal action to collect on payday loans in these states. The representations were material because threats of possible legal action could have an impact on a consumer's decision regarding whether and when to make payment. In response to these findings, Supervision directed the institutions to stop engaging in the deceptive conduct.

Examiners also found that lenders engaged in deceptive acts or practice by making false threats related to garnishment in collections communications. Lenders used the term ''garnishment'' in communications with consumers when referring to voluntary wage deduction process. These representations misled or were likely to mislead reasonable consumers by giving the false impression they would be subject to an involuntary legal garnishment process if they did not make payment. In fact, consumers could revoke voluntary wage deduction consent at will under the terms of the loan agreement and prevent deductions from occurring. Consumers acting reasonably would believe that the lenders express references to the possibility of garnishment accurately reflected what might happen absent the consumers making payment. The representations were material because they may have affected a consumer's decision regarding whether and when to make payment and whether to revoke their consent to the voluntary wage deduction process. In response to these findings, the entities were required to stop engaging in the deceptive conduct.

In addition, examiners found that periodic statements provided to borrowers falsely stated, ''if we do not receive your minimum payment by the date listed above, you may have to pay a $25 late fee.'' Such representations misled or were likely to mislead borrowers into reasonably believing that they could be charged late fees, when in fact lenders did not assess late fees in connection with the product. The representations were material because they were likely to affect consumers' decisions about whether and when to make payments. In response to these findings, Supervision directed the lenders to stop engaging in the deceptive conduct.

2.10.3 Unauthorized Wage Deductions

Examiners found that lenders engaged in unfair acts or practices with respect to consumers who signed voluntary wage deduction agreements by sending demand notices to consumers' employers that incorrectly conveyed that the employer was required to remit to the lenders from the consumer's wages the full amount of the consumer's loan balance. In fact, the consumer had agreed to permit the lenders only to seek a wage deduction in the amount of the individual scheduled payment due. The lenders then collected wages from the consumers' employers in amounts exceeding the single payment authorized by the consumer. This wage collection practice caused substantial injury to consumers who incurred monetary injury by having amounts deducted from their wages in excess of what they had authorized. The consumers could not have reasonably avoided the injury, which was caused by the lenders seeking and obtaining wage deductions in excess of those authorized by the consumers. The benefits to the lenders of collecting unauthorized amounts do not outweigh the injuries to the consumers in the form of lost wages. In response to these findings, Supervision directed lenders to stop engaging in the practice and provide remediation to impacted borrowers.

2.10.4 Misrepresentations Regarding the Impact of Payment of Debt in Collections

Examiners found that lenders engaged in deceptive acts or practices when they misrepresented to borrowers the impact that payment or nonpayment of debts in collection may have on the sale of the debt to a debt buyer and the subsequent impact on the borrower's credit reports. The lenders made representations about debt sale, credit reporting practices, and corresponding effects on consumer creditworthiness that misled or were likely to mislead the consumer. Their agents asserted or implied that making a payment would prevent referral to a third-party debt buyer and a negative credit impact. However, these agents had no basis to predict the consumer's credit situation or a potential debt buyer's furnishing practices, the lender's contracts with debt buyer prohibited furnishing to a CRC, and the debt was not in fact sold. It was reasonable for a consumer experiencing repayment difficulty to interpret the representations to mean that not making a payment would cause a third party to subsequently report adverse credit information and worsen their creditworthiness. The representations were material because they were likely to affect the consumer's choices or conduct regarding the loan. In response to these findings, Supervision directed

the entities to stop engaging in the deceptive conduct.

2.10.5 Risk of Harm to Consumers Protected by the Military Lending Act

Examiners found that installment lenders created a risk of harm to borrowers protected by the Military Lending Act by, before engaging in loan transactions, and contrary to their policies, failing to confirm that several thousand borrowers were not covered borrowers under the Military Lending Act as implemented by Department of Defense regulations.[71] These risks included potentially, originating loans to covered borrowers at rates and terms impermissible under the Military Lending Act; not providing covered borrowers with required disclosures; including in loan agreements prohibited mandatory arbitration clauses; and failing to limit certain types of repeat or extended borrowing. In response to these findings, Supervision directed lenders to change their practices to prevent these risks.

2.10.6 Failure To Retain Evidence of Compliance With Disclosure Requirements Under Regulation Z

Examiners found that lenders failed to retain for two years evidence that they delivered clear and conspicuous closed-end loan disclosures in writing before consummation of the transaction, in a form that consumers may keep, in violation of the record-retention provision of Regulation Z,[72] and creating a risk of a violation of the general disclosure requirements of Regulation Z.[73] Copies of disclosures in loan files did not include evidence of when or how lenders delivered disclosures to borrowers. And lenders were unable to produce evidence that, for electronically signed contracts, disclosures were delivered to consumers in a form they may keep before loan consummation. Lenders' compliance procedures did not require delivery of loan disclosures to consumers in a form they may keep before consummation. In response to these findings, Supervision directed lenders to update compliance management systems to ensure clear and conspicuous disclosures are provided in writing in a form the consumer may keep before consummation and evidence of compliance is retained, consistent with Regulation Z, for all disclosure channels, including electronic or keypad.

[71] 10 U.S.C. 987 and 32 CFR 232.1 *et seq.*

[72] 12 CFR 1026.25.

[73] 12 CFR 1026.17(a)(1) and (b).

2.11 Remittances

The CFPB evaluated both depository and non-depository institutions for compliance with the Electronic Funds Transfer Act (EFTA) and its implementing Regulation E, including subpart B (Remittance Rule).[74]

2.11.1 Failure To Develop Policies and Procedures To Ensure Compliance With the Remittance Rule's Error Resolution Requirements

The Remittance Rule states that a remittance transfer provider shall develop and maintain written policies and procedures that are designed to ensure compliance with the error resolution requirements applicable to remittance transfers. Some institutions did not develop written policies and procedures designed to ensure compliance. This issue was noted in prior editions of *Supervisory Highlights* and continues to be an issue with institutions.[75]

For example, some institutions used their anti-money laundering compliance policy in lieu of a specific policy tailored to the Remittance Rule requirements. The anti-money laundering policy and procedure included some basics, like identifying some covered Remittance Rule errors and the basic timeframes remittance providers had to investigate and resolve error notices. But they were not substitutes for Remittance Rule policies. They did not provide detailed guidance to employees on how to distinguish notices of error, the handling of which are subject to specific Remittance Rule requirements, from other complaints. They did not make clear employees should provide notifications that are required by the Remittance Rule to consumers when the institutions determined an error, no error, or a different error occurred. The policies also did not alert employees as to the remedies available to consumers under the Remittance Rule and articulated remedies different than those required by the Remittance Rule. Other institutions provided policies that indicated the institutions knew of the Remittance Rule and its requirements and had manuals to cover Remittance Rule compliance. However, these institutions did not develop procedures that would put these policies into effect. Specifically, the manuals did not provide adequate guidance to employees to resolve error notices in a consistent and compliant manner. Recitation of Remittance Rule requirements without greater detail on how to effectuate compliance does not ensure compliance as the Remittance Rule requires.

In response to these findings, institutions updated their policies and procedures during or after the conclusion of the examinations.

[74] 15 U.S.C. 1693 *et seq.;* 12 CFR 1005.30 *et seq.*

[75] CFPB, Supervisory Highlights, Issue 26, Spring 2022, *available at https://www.consumerfinance.gov/data-research/research-reports/supervisory-highlights-issue-26-spring-2022/.*

3. Supervisory Program Developments

3.1 Recent CFPB Supervision Program Developments

Set forth below are recent supervision program developments including circulars, bulletins, advisory opinions, policy statements and exam procedures that have been issued since the last regular edition of *Supervisory Highlights.*

3.1.1 CFPB Nonbank Supervisory Authorities

The CFPB has supervisory authority over nonbanks in the mortgage, private education, and payday loan markets, regardless of the entities' size.[76] The CFPB also has supervisory authority over larger participants of markets for other consumer financial products or services defined by rule.[77] Additionally, the CFPB has supervisory authority over nonbank covered persons it has reasonable cause to determine, by order, after notice and a reasonable opportunity to respond, based on complaints or information from other sources, that the person is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services.[78] The CFPB issued a rule implementing this provision of the CFPA in 2013. These processes were amended after notice and comment in a final procedural rule in November 2022.[79] Since the amended rule was finalized, the CFPB has entered into discussions with several entities across markets regarding the CFPB's supervision program and its benefits, including identifying potential compliance issues before they become significant. And the CFPB has issued several Notices of Reasonable Cause

[76] 12 U.S.C. 5514(a)(1)(A), (D), and (E).

[77] 12 U.S.C. 5514(a)(1)(B). To date the CFPB has issued larger participant rules for the consumer reporting, debt collection, student loan servicing, international money transfer, and automobile financing markets. *See* 12 CFR part 1090.

[78] 12 U.S.C. 5514(a)(1)(C).

[79] 12 CFR part 1091; 78 FR 40352 (July 3, 2013); the procedural rule is available at *https://s3.amazonaws.com/files.consumerfinance.gov/f/documents/cfpb_supervisory-risk-determinations-rule_2022-11.pdf.*

commencing the risk-based supervision process under the rule. As a result of these activities, several entities have voluntarily consented to the CFPB's supervisory authority.

Additionally, the CFPB is conducting, or has scheduled, supervisory examinations of one or more data aggregators, including larger participants in the consumer reporting market.

3.1.2 CFPB Issued Circular Regarding Reopening Deposit Accounts That Consumers Previously Closed

On May 10, 2023, the CFPB issued a circular to emphasize that a financial institution's unilateral reopening of deposit accounts that consumers previously closed can constitute a violation of the CFPA's prohibition on unfair acts or practices.[80]

3.1.3 CFPB Issued an Advisory Opinion Addressing Protection of Homeowners From Illegal Collection Tactics on Zombie Mortgages

On April 26, 2023, the CFPB issued an advisory opinion on debt collectors, covered by the FDCPA, threatening to foreclose on homes with mortgages past the statute of limitations.[81] The advisory opinion clarifies that a covered debt collector who brings or threatens to bring a State court foreclosure action to collect a time-barred mortgage debt may violate the FDCPA and its implementing regulation.

3.1.4 CFPB Issued Policy Statement on Abusive Acts or Practices

On April 3, 2023, the CFPB issued a policy statement to explain how the CFPB analyzes the elements of abusiveness through relevant examples, with the goal of providing an analytical framework to fellow government enforcers and to the market for how to identify violative acts or practices.[82]

3.1.5 CFPB Issued Bulletin 2023–01: Unfair Billing and Collection Practices After Bankruptcy Discharged of Certain Student Loan Debts

On March 16, 2023, the CFPB issued a bulletin on unfair billing and collection practices after bankruptcy discharges of certain student loan debt.[83] The bulletin details examiners' findings that student loan servicers who collected on student loans that were discharged by a bankruptcy court had engaged in an unfair act or practice in violation of the CFPA. The CFPB issued this bulletin to notify regulated entities how the CFPB intends to exercise its enforcement and supervisory authorities on this issue.

3.1.6 CFPB Issued an Advisory Opinion To Protect Mortgage Borrowers From Pay-to-Play Digital Mortgage Comparison Shopping Platforms

On February 7, 2023, the CFPB issued an advisory opinion outlining how companies that operate digital mortgage comparison-shopping platforms violate the Real Estate Settlement Procedures Act when they steer shoppers to lenders by using pay-to-play tactics rather than providing shoppers with comprehensive and objective information.[84]

3.1.7 CFPB Issued Circular on Unlawful Negative Option Marketing Practices

On January 19, 2023, the CFPB issued a circular that states that persons engaged in negative option marketing practices may violate the prohibition on unfair, deceptive, or abusive acts or practices in the CFPA.[85] Negative option marketing practices may violate that prohibition where a seller (1) misrepresents or fails to clearly and conspicuously disclose the material terms of a negative option program; (2) fails to obtain consumers' informed consent; or (3) misleads consumers who want to cancel, erects unreasonable barriers to cancellation, or fails to honor cancellation requests that comply with its promised cancellation procedures.

3.1.8 CFPB Released Updates to Mortgage Servicing Exam Procedures

On January 18, 2023, the CFPB released its updated mortgage servicing exam procedures.[86] The examination procedures describe the types of information that CFPB examiners gather to evaluate mortgage servicers' policies and procedures; assess whether servicers are complying with applicable laws; and identify risks to consumers related to mortgage servicing. The updated Examination Procedures include CFPB guidance released since the last update in June 2016.

4. Remedial Actions

The CFPB's supervisory activities resulted in and supported the below enforcement actions.

4.1.1 Citizens Bank

On May 23, 2023, the CFPB reached a settlement to resolve allegations that Citizens Bank violated consumer financial protection laws and rules that protect individuals when they dispute credit card transactions.[87] The CFPB alleges that Citizens Bank failed to properly manage and respond to customers' credit card disputes and fraud claims. The order requires Citizens Bank to pay a $9 million civil money penalty.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2023–16764 Filed 8–4–23; 8:45 am]

BILLING CODE 4810–AM–P

[80] CFPB Circular 2023–02, Reopening deposit accounts that consumers previously closed, *available at https://www.consumerfinance.gov/compliance/circulars/consumer-financial-protection-circular-2023-02-reopening-deposit-accounts-that-consumers-previously-closed/.*

[81] CFPB Advisory Opinion, FDCPA; Time-Barred Debt, *available at https://www.consumerfinance.gov/about-us/newsroom/cfpb-issues-guidance-to-protect-homeowners-from-illegal-collection-tactics-on-zombie-mortgages/.*

[82] CFPB Policy Statement on Abusive Acts or Practices, *available at https://www.consumerfinance.gov/compliance/supervisory-guidance/policy-statement-on-abusiveness/.*

[83] CFPB, Unfair Billing and Collection Practices After Bankruptcy Discharges or Certain Student Loan Debts, *available at https://s3.amazonaws.com/files.consumerfinance.gov/f/documents/cfpb_unfair-billing-collection-bankruptcy-student-loan-debt_2023-01.pdf.*

[84] CFPB, Digital Mortgage Comparison-Shopping Platforms and Related Payments to Operators, *available at https://s3.amazonaws.com/files.consumerfinance.gov/f/documents/cfpb_respa-advisory-opinion-on-online-mortgage-comparison-shopping-tools_2023-02.pdf.*

[85] CFPB Circular 2023–01, Unlawful negative option marketing practices, *available at https://www.consumerfinance.gov/compliance/circulars/consumer-financial-protection-circular-2023-01-unlawful-negative-option-marketing-practices//.*

[86] CFPB, Mortgage Servicing Examination Procedures, *available at https://www.consumerfinance.gov/compliance/supervision-examinations/mortgage-servicing-examination-procedures/.*

[87] *Bureau of Consumer Financial Protection* v. *Citizens Bank, N.A.,* Stipulated Final Judgment and Order, *available at https://www.consumerfinance.gov/enforcement/actions/citizens-bank/.*

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 2023–0031]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigation of Smart Toys and Additional Toys Through Child Observations

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: Pursuant to the Paperwork Reduction Act of 1995 (PRA), the Consumer Product Safety Commission

(CPSC or Commission) invites public comment about a request for approval from the Office of Management and Budget (OMB) for a new information collection. The proposed collection is associated with CPSC's investigation, through child observations and caregiver questionnaires, of smart toys and additional toys (take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives) to consider children's ability to interact with toys as the manufacturer intended and assist in updating CPSC's age determination guidelines. Before CPSC can collect this information from the public, we must solicit public comment on this proposed collection of information and receive OMB approval. *This notice describes the collection of information for which CPSC intends to seek OMB approval.*

DATES: Submit written or electronic comments on the collection of information by October 6, 2023.

ADDRESSES: You can submit comments, identified by Docket No. CPSC–2023–0031, by any of the following methods:

Electronic Submissions: CPSC encourages you to submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except as described below.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov;* insert the docket number, CPSC–2023–0031, into the ''Search'' box; and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: *CGillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning the proposed collection of information. In this notice we provide the estimated burden associated with a new information collection for CPSC's investigation, through child observations and caregiver questionnaires, of smart toys and additional toys to consider children's ability to interact with toys as the manufacturer intended, to inform CPSC's age determination guidelines.[1] Under the PRA, an agency must publish the following information:

- A title for the collection of information;
- A summary of the collection of information;
- A brief description of the need for the information and the proposed use of the information;
- A description of the likely respondents and proposed frequency of response to the collection of information;
- An estimate of the burden that will result from the collection of information; and
- Notice that comments may be submitted to the agency and OMB.

44 U.S.C. 3507(a)(1)(D). In accordance with this requirement, the Commission provides the following information:

Title: Investigation of Smart Toys and Additional Toys Through Child Observations.

OMB Control Number: New.

Type of Request: New information collection requirement.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 1 year from date of approval.

Summary of the Collection of Information: CPSC proposes to conduct individual in-person data collection sessions with up to 60 children aged 2–4 years old and their caregivers, for a total of 120 participants. Caregivers will answer a series of screening questions to determine if the caregiver and child meet the criteria for enrollment in the study. CPSC will enroll in the data collection study children and caregivers who meet the screening criteria and are willing to participate.

Over two in-person sessions, researchers will collect data primarily through direct human observations of children's interactions with toys and caregivers' responses to questionnaires. In each session, researchers will introduce children to 4–5 toys chosen from 6 toy categories (smart toys, take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives). The researcher will demonstrate for the child how to use each toy and then document the child's play patterns with the toy, noting the child's ability to interact with each toy as the manufacturer intended. Researchers will use coding checklists to document real-time observations of the child's interactions with the toys, in the form of concrete behaviors across different modalities, such as gross motor (*e.g.,* turns figurines head), fine motor (*e.g.,* slides switch on/off), and behavioral (*e.g.,* feeding an animal, engages in pretend play with one or multiple figurines), which demonstrate the child's ability to use the toy as intended.

Caregivers will respond to researcher questions about the caregiver's perception of their child's ability to interact with the selected toys as intended, potential purchasing decisions for the specific toys, and whether the caregiver would demonstrate how to play with the toys or some of the components as the manufacturer intends. Researchers will record on paper forms their observations of children's interactions and caregiver's responses to questions about the toys.

Researchers will randomize the presentation order of the toys for each caregiver/child pair to preclude any effects of sequence and control for learning or fatigue that might take place. Also, researchers will use video cameras to record each child's interaction with a toy. Researchers will use the video as a backup reference for real time coding.

Researchers will separate out all personally identifiable information from data collected. Also, researchers will separate out from collected information all identifying information from the initial screening, as well as scheduling. This information will be kept on a secure server in password protected files and discarded by researchers when

[1] On August 1, 2023, the Commission voted (4–0) to publish this notice.

no longer needed. At the end of each session, researchers will save the video data onto a secure server. Researchers will enter data recorded on the paper forms into a secure database, which also will be kept on a secure server. Researchers will limit access to this information and will summarize all information collected during the sessions using generic categories and summary statistics.

Description of the Need for the Information and Proposed Use of the Information: Created in 1972, the CPSC is an independent federal regulatory agency with a public health and safety mission to protect the public from unreasonable risks of injury and death from consumer products used in and around the home, in recreation, and in schools. As part of this statutory mandate, CPSC is authorized to conduct research on consumer products and behavior to identify and address product safety hazards, as well as to develop efficient and effective means of bringing about safety improvements. This information collection supports the Commission's strategic goal of safety.

Age-appropriate toys are important for the physical, intellectual, and socioemotional development of children. Age-appropriate toys can help children learn, develop imaginative capacities, and refine motor coordination. However, interacting with toys intended for older children poses a potential risk for the child to be seriously or fatally injured. In 2021, an estimated 206,400 toy-related injuries were treated in U.S. hospital emergency rooms.[2] Of the 206,400 toy-related injuries, an estimated 74% happened to children 14 years of age or younger; 69% occurred to children 12 years of age or younger; and 37% happened to children 4 years of age or younger.

To identify a toy's safety hazards, the CPSC Division of Human Factors first determines the intended age group of potential users. CPSC considers age determinations for toys to be of paramount importance because age-grading and labeling can be used to assist consumers in making purchasing decisions, and also serve as the basis for the toy's regulatory requirements and the associated testing parameters. For example, toys intended for children under 8 years of age are required to undergo use and abuse tests based on actual use and misuse by children of that age. Test specifications vary for different age groups (*i.e.,* children 18 months and younger, 19–36 months, and 37–95 months). Toys intended for children younger than 3 years old cannot possess small parts. Additionally, since 2008, CPSC regulations require lead and phthalates limitations for many products intended for children 12 years of age.

CPSC staff consider numerous toy characteristics when determining the intended age, including the physical characteristics of the toy (*e.g.,* size and weight of the toy and its components), the cognitive requirements for using the toy as intended, the fine motor or other physical skills required to use the toy as the manufacturer intended, and the toy's theme and appearance. CPSC's *Age Determination Guidelines: Relating Consumer Product Characteristics to the Skills, Play Behaviors, and Interests of Children (Guidelines),* available at *https://www.cpsc.gov/content/2020-Age-Determination-Guidelines,* provide details and examples for each of these characteristics for different age groups. Manufacturers can use the *Guidelines* to generate an intended age during a toy's design phase. Manufacturers can also use the *Guidelines* to accurately age label a product, which promotes safety by informing consumer purchasing and toy-safety decisions (meaning which toys are appropriate to allow a child to play with).

Although the *Guidelines* include extensive information about a large variety of toys, some toy categories are not well covered in the *Guidelines* because they include toys that are new to the U.S. market since the research that went into the 2020 version of the Guidelines. Conversely, while smart toys are discussed in the *Guidelines,* this category of toys evolves rapidly, so the *Guidelines* may not represent what is currently in the market. Other toys such as figurines, interlocking building sets, and musical toys are discussed in the *Guidelines,* though not extensively. This data collection will add to the information about selected toys in six toy categories (smart toys, take-apart vehicles, musical instruments, figurines, plush toys with electronic components, and manipulatives), and enrich CPSC's understanding regarding the ages of children who are interested in these toys and who possess the skills and cognitive ability to use them as intended. This data collection will provide information to help CPSC determine the developmentally appropriate ages for selected toys. Ultimately, the data collection will inform the various stakeholders who use the information contained in the *Guidelines.*

Affected Public: Children between 2–4 years and their caregivers.

Estimated Number of Respondents: 60 children and 60 caregivers, totaling 120 individuals.

Frequency: One-time data collection that will take place over two in-person sessions. The first session will last 80 minutes, and the second session will last 80 minutes.

Estimated Total Annual Burden Hours: CPSC plans to pilot test the study with 4 participants (2 caregivers and 2 children) with a maximum time burden of 2.67 hours per person (10.68 hours). CPSC also assumes a 15-minute completion time for the recruitment screener questionnaire to be filled out by a maximum of 100 people, to select 60 adult participants (25 hours).

Once selected for the study, CPSC estimates that the total time for each respondent pair (caregiver/child) to participate in the data collection will likely not be more than 160 minutes. Therefore, each participant has a maximum time burden of 2.67 hours. Data collection duration for each respondent will be 2.67 hours, or a total of 160 hours for 60 respondent pairs. Each respondent pair will not incur any reporting costs from the information collection. The pair also will not incur a record keeping burden or record keeping costs from this information collection. We will assume an hourly wage rate of $31.54 for each respondent pair (caregiver and child).[3]

Accordingly, the total burden hours to recruit participants and for selected respondents to participate is 356 hours (recruitment screening time (25 hours), pilot study (10.68 hours), and the main study (2.67 hours × 120 participants)).

The total cost of this collection to the federal government is $93,345 annually. This represents 6 months of staff time. This amount includes federal employee salaries and benefits. No travel costs are associated with the collection. This estimate uses an annual salary of $126,949 (the equivalent of a GS–13, Step 5 employee, in the Washington, DC area in 2023)[4] which represents 68.0 percent of the employer costs for employee compensation. The remaining 32.0 percent of employer costs are added for benefits (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' March 2023, percentage of wages and salaries for all civilian management, professional, and

[2] Consumer Product Safety Commission: Toy-Related Deaths and Injuries, Calendar Year 2021. November, 2022: Toy-Related Deaths and Injuries, Calendar Year 2021; available at: *https://www.cpsc.gov/Research--Statistics/Toys-and-Childrens-Products.*

[3] *https://www.bls.gov/oes/current/oes_va.htm#00-0000.*

[4] *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB.pdf.*

related employees),[5] for a total annual compensation per FTE of $186,690.

Estimated Total Annual Burden Cost: $104,573.24 (Respondents: $11,228.24 (31.54/hr. × 356 hours) + Federal Government: $93,345).

Comments: CPSC requests that interested parties submit comments regarding this proposed information collection (see the **ADDRESSES** section at the beginning of this notice). Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission specifically invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;
- The accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, utility, and clarity of the information the Commission proposes to collect;
- Ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques when appropriate, and other forms of information technology;
- The estimated burden hours associated with child toy observations and caregiver surveys, including any alternative estimates; and
- The estimated respondent cost other than burden hour cost.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–16790 Filed 8–4–23; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Women in the Services; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) will take place.

DATES: DACOWITS will hold an open-to-the-public meeting—Tuesday, September 12, 2023, from 8:00 a.m. to 10:15 a.m. (EST) and Wednesday, September 13, 2023, from 8:00 a.m. to 12:00 p.m. (EST).

ADDRESSES: The meeting will take place at the Association of the United States Army Conference Center, located at 2425 Wilson Boulevard, Arlington, Virginia 22201. The meeting will also be held virtually. To participate in the meeting, see the Meeting Accessibility section for instructions.

FOR FURTHER INFORMATION CONTACT: LTC Samantha Frazier, Designated Federal Officer (DFO), (202) 650–2943 (voice), *Samantha.j.frazier11.mil@mail.mil* (email). The most up-to-date changes to the meeting agenda can be found on the website: *https://dacowits.defense.gov.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available at the DACOWITS website, *https://dacowits.defense.gov/.* Materials presented in the meeting may also be obtained on the DACOWITS website.

Purpose of the Meeting: The purpose of the meeting is for the DACOWITS to receive briefings and have discussions on topics related to the recruitment, retention, employment, integration, well-being, and treatment of women in the Armed Forces of the United States. Additionally, the Committee will vote on its 2023 recommendations.

Agenda: Tuesday, September 12, 2023, from 8:00 a.m. to 10:15 a.m.—Welcome, Introductions, Announcements, Request for Information Status Update, Briefing, Public Comment Period, and DACOWITS discussion.

Wednesday, September 13, 2023, from 8:00 a.m. to 12:00 p.m.—Welcome, Introductions and Announcements, Voting on 2023 recommendations.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to availability of space, from 8:00 a.m. to 10:15 a.m. on September 12, 2023, and from 8:00 a.m. to 12:00 p.m. on September 13, 2023. The meeting will also be streamed by videoconference. The number of participants is limited and is on a first-come basis. Any member of the public who wishes to participate via videoconference must register by contacting DACOWITS at *osd.pentagon.ousd-p-r.mbx.dacowits@mail.mil* or by contacting Mr. Robert Bowling at (703) 380–0116 no later than Tuesday, September 5, 2023. Once registered, the videoconference information will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Robert Bowling no later than Tuesday, September 5, 2023, so appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the FACA, interested persons may submit a written statement to the DACOWITS. Individuals submitting a written statement must submit their statement no later than 5:00 p.m., Tuesday, September 5, 2023, to Mr. Robert Bowling (703) 380–0116 (voice) or to *robert.d.bowling1.mil@mail.mil* (email). Mailing address is 4800 Mark Center Drive, Suite 04J25–01, Alexandria, VA 22350. Members of the public interested in making an oral statement, must submit a written statement. If a statement is not received by Tuesday, September 5, 2023, it may not be provided to or considered by the Committee during this quarterly business meeting. After reviewing the written statements, the Chair and the DFO will determine if the requesting persons are permitted to make an oral presentation. The DFO will review all timely submissions with the DACOWITS Chair and ensure they are provided to the members of the Committee.

Dated: August 1, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–16727 Filed 8–4–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Board of Actuaries; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense Board of Actuaries, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

[5] *https://www.bls.gov/news.release/archives/ecec_06162023.pdf.*

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Department of Defense Board of Actuaries will take place.

DATES: Open to the public Friday, September 29, 2023, from 10:00 a.m. to 12:00 p.m.

ADDRESSES: This meeting will be held virtually. For information regarding how to access the meeting, please contact Inger Pettygrove (703) 225–8803 or *Inger.m.pettygrove.civ@mail.mil* as soon as possible.

FOR FURTHER INFORMATION CONTACT: Inger Pettygrove, (703) 225–8803 (Voice), *inger.m.pettygrove.civ@mail.mil* (Email). Mailing address is Defense Human Resources Activity, DoD Office of the Actuary, 4800 Mark Center Drive, STE 03E25, Alexandria, VA 22350–8000. Website: *https://actuary.defense.gov/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is for the Board to review DoD actuarial methods and assumptions to be used in the valuation of the Education Benefits Fund in accordance with the provisions of section 183, section 2006, chapter 74 (10 U.S.C. 1464 *et seq.*).

Agenda

Education Benefits Fund
1. Fund Overview
2. September 30, 2022, Valuation Proposed Economic Assumptions *
3. September 30, 2022, Valuation Proposed Methods and Assumptions—Reserve Programs *
4. September 30, 2022, Valuation Proposed Methods and Assumptions—Active-Duty Programs *
5. Developments in Education Benefits

* Board approval required

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public.

Written Statements: Persons desiring to attend the DoD Board of Actuaries meeting or make an oral presentation or submit a written statement for consideration at the meeting must notify Inger Pettygrove at (703) 225–8803, or *inger.m.pettygrove.civ@mail.mil,* by September 15, 2023.

Dated: August 1, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–16726 Filed 8–4–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Office of the Secretary

National Security Education Board (NSEB); Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness (USD(P&R)), Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the National Security Education Board will take place.

DATES: Open to the public on Thursday, September 7, 2023 from 11:45 a.m. Eastern Standard Time (EST) to 5:00 p.m. EST.

ADDRESSES: The meeting will be held at 1350 Eye Street NW, Washington, DC 22205. Please contact Ms. Alison Patz by phone, (571) 329–3894, or email (*alison.m.patz.civ@mail.mil*) for information about attending the meeting. FOR

FOR FURTHER INFORMATION CONTACT: Ms. Alison Patz, (571) 329–3894 (Voice), *alison.m.patz.civ@mail.mil* (Email). Mailing address is National Security Education Program, 4800 Mark Center Drive, Suite 08G08, Alexandria, VA 22350–7000. Website: *https://dlnseo.org/Governance/NSEB.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to review and make recommendations to the Secretary of Defense concerning requirements established by the David L. Boren National Security Education Act, Title VII of Public Law 102–183, as amended.

Agenda: Thursday, September 7, 2023 from 11:45 a.m. to 5:00 p.m. the NSEB will begin an open session with opening remarks by Dr. Clare Bugary, the Designated Federal Official (DFO), and the Honorable Shawn Skelly, Assistant Secretary of Defense for Readiness, who will Chair the meeting. The NSEB will receive a briefing on the class of 2023 Boren Scholars and Fellows and updates regarding Project Global Officer summer 2023 programming. The meeting will continue with a mission highlight from the National Language Service Corps, followed by working group discussion. The meeting's final session will be an overview of the English for Heritage Language Speakers (EHLS) program, with an EHLS Open-Source Analysis Project briefing. General discussion and closing remarks by the Chair and the DFO will adjourn the meeting.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public, subject to the availability of space.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Alison Patz at *alison.m.patz.civ@mail.mil* (email) or (571) 329–3894 (voice) no later than Wednesday, August 23, 2023, so that appropriate arrangements can be made.

Written Statements: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150. Pursuant to 41 CFR 102–3.140 and sections 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the DoD National Security Education Board about its mission and functions. Written statements may be submitted at any time or in response to the stated agenda of the planned meeting. All written statements shall be submitted to the point of contact at the email address or phone number listed in the **FOR FURTHER INFORMATION CONTACT** section, and this individual will ensure that the written statements are provided to the membership for their consideration. Statements being submitted in response to the agenda items mentioned in this notice must be received by the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section at least five calendar days prior to the meeting that is the subject of this notice. Written statements received after this date may not be provided to or considered by the National Security Education Board until its next meeting.

Dated: August 1, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–16730 Filed 8–4–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–517–000]

Discovery Gas Transmission LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on July 24, 2023, Discovery Gas Transmission LLC (Discovery) filed a prior notice request for authorization, in accordance with sections 157.205, 157.206 and 157.208, of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act and Discovery's blanket certificate issued in Docket No. CP96–719–000,[1] to install an additional slug catcher and other ancillary facilities to existing system located in Lafourche Parish, Louisiana (Shenandoah—Larose Slug Catcher Project). Specifically, Discovery proposes to increase its handling capacity and operational flexibility by installing a new 11,000-barrel slug catcher directly adjacent to the existing 7,500-barrel slug catcher adjacent to Discovery Producer Services LLC's existing Larose Gas Processing Plant. Discovery estimates the cost of the Project to be approximately $24 million, all as more fully set forth in its request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room. For assistance, contact the Federal Energy Regulatory Commission at *FercOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY (202) 502–8659.

Any questions concerning this request should be directed to: Georgia Clark, Regulatory Analyst Sr., Discovery Gas Transmission LLC, 2800 Post Oak Boulevard, Houston, Texas, 77056, or call (346) 388–0663, or via email to *Georgia.clark@williams.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on October 2, 2023. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is October 2, 2023. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is October 2, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before October 2, 2023. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

[1] *Discovery Producers Services LLC et al,* 78 FERC ¶ 61,194 (1997).

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP23–517–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP23–517–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other method: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Georgia Clark, Regulatory Analyst Sr., Discovery Gas Transmission LLC, 2800 Post Oak Boulevard, Houston, Texas 77056, or call (346) 388–0663, or via email to *Georgia.clark@williams.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: August 1, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–16777 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–131–000]

East Tennessee Natural Gas, LLC; Notice of Waiver Period for Water Quality Certification Application

On July 20, 2023, East Tennessee Natural Gas, LLC submitted to the Federal Energy Regulatory Commission (Commission) a copy of its application for a Clean Water Act section 401(a)(1) water quality certification filed with the Tennessee Department of Environment and Conservation, in conjunction with the above captioned project. Pursuant to 40 CFR 121.6 and section 157.22(b) of the Commission's regulations,[1] we hereby notify the Tennessee Department of Environment and Conservation of the following:

Date of Receipt of the Certification Request: June 26, 2023.

Reasonable Period of Time to Act on the Certification Request: June 26, 2024.

If the Tennessee Department of Environment and Conservation fails or refuses to act on the water quality certification request by the above waiver date, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: July 31, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–16709 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 157.22.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator Status

	Docket Nos.
Anemoi Energy Storage, LLC	EG23–142–000
Ebony Energy Storage, LLC	EG23–143–000
Clearwater Wind II, LLC	EG23–144–000
Johnson County Power, LLC	EG23–145–000
RW Miller Power, LLC	EG23–146–000
Jack County Power, LLC	EG23–147–000
Boomtown Solar Energy LLC	EG23–148–000
Delta's Edge Lessee, LLC	EG23–149–000
Solar Partners XI, LLC	EG23–150–000
Horizon Solar, LLC	EG23–151–000
Sun Pond, LLC	EG23–152–000
Oak Lessee, LLC	EG23–153–000
Fox Squirrel Solar LLC	EG23–154–000
Huck Finn Solar, LLC	EG23–155–000
Harvest Gold Solar Power, LLC	EG23–156–000
SMT Alamo LLC	EG23–157–000
SMT Santa Rosa LLC	EG23–158–000
SMT Bay City LLC	EG23–159–000
SMT Elsa LLC	EG23–160–000
SMT Mercedes LLC	EG23–161–000
SMT Mission LLC	EG23–162–000
SMT Los Fresnos LLC	EG23–163–000
SMT Rio Grande LLC	EG23–164–000
SMT Rio Grande II LLC	EG23–165–000
SMT Harlingen II LLC	EG23–166–000
Appaloosa Solar I, LLC	EG23–167–000
Pome BESS LLC	EG23–168–000
Three Corners Solar, LLC	EG23–169–000
Three Corners Prime Tenant, LLC.	EG23–170–000
BE-Pine 1 LLC	EG23–171–000
Horus West Virginia I, LLC	EG23–172–000
Horus Louisiana I, LLC	EG23–173–000

Take notice that during the month of July 2023, the status of the above-captioned entities as Exempt Wholesale Generators became effective by operation of the Commission's regulations. 18 CFR 366.7(a) (2022).

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16786 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14775–005]

Marine Renewable Energy Collaborative of New England; Notice of Intent To Prepare an Environmental Assessment

On June 1, 2023, Marine Renewable Energy Collaborative of New England filed an application for a hydrokinetic pilot project license to connect the existing Bourne Tidal Hydrokinetic Test Site (project) to the power grid. The project would be located in the Cape Cod Canal near the Town of Bourne, in

Barnstable County, Massachusetts. The project would be within the boundary of the Cape Cod Canal Navigation Project, which is administered by the U.S. Army Corps of Engineers.

In accordance with the Commission's regulations, on June 16, 2023, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA notice, staff does not anticipate that licensing the project would constitute a major Federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to license the project.

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA.	September 2023 [1].
Comments on EA	October 2023.

[1] The Council on Environmental Quality's (CEQ) regulations under 40 CFR 1501.10(b)(1) require that EAs be completed within 1 year of the Federal action agency's decision to prepare an EA. This notice establishes the Commission's intent to prepare an EA for the Bourne Tidal Hydrokinetic Test Site Project. Therefore, in accordance with CEQ's regulations, the EA must be issued within 1 year of the issuance date of this notice.

Dated: July 31, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–16707 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2523–000]

SR Lambert I, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Lambert I, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16782 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL23–88–000]

Energy Harbor LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On July 31, 2023, the Commission issued an order in Docket No. EL23–88–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation into whether Energy Harbor LLC's Rate Schedule 1 and Rate Schedule 2 are unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Energy Harbor LLC,* 184 FERC ¶ 61,068 (2023).

The refund effective date in Docket No. EL23–88–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL23–88–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and

Procedure, 18 CFR 385.214 (2022), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16785 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2526–000]

GreenStruxure LOR008, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GreenStruxure LOR008, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16780 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2522–000]

SR Georgetown, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Georgetown, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16783 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2524–000]

SR Lambert II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Lambert II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16781 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–519–000]

Rio Bravo Pipeline Company, LLC; Notice of Amendment of Authorization and Establishing Intervention Deadline

Take notice that on July 20, 2023, Rio Bravo Pipeline Company, LLC (Rio Bravo), 915 N Eldridge Parkway, Suite 1100, Houston, Texas 77079, filed an application under section 7(c) of the Natural Gas Act (NGA), and part 157 of the Commission's regulations requesting authorization for its Adjusted Project. The Adjusted Project consists of four minor route adjustments, all in Texas: (i) the U.S.Fish and Wildlife Service (USFWS) Route Adjustment in Willacy Co. (9.6 miles), (ii) the North Floodway Route Adjustment in Willacy Co. (0.6 miles), (iii) the Arroyo Colorado Route Adjustment in Willacy and Cameron

Cos. (0.8 miles), and (iv) the Terminus Adjustment in Cameron Co. (0.6 miles) as well as a modification to the design of the portions of the Project mainline pipelines on a majority of the route located in Class 1 areas consistent with PHMSA regulations.

The Adjusted Project will minimize impacts to potential ocelot habitat, address USFWS concerns regarding impacts on this habitat, address agency and landowner concerns, avoid recently constructed infrastructure, enhance safety, affect fewer wetlands, forest lands, and prime farmland soils, and align the Rio Bravo Pipeline Project with the updated design of the LNG Terminal to which it will interconnect. Rio Bravo states that the Adjusted Project will not affect the previously authorized capacity, rates or services, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room. For assistance, contact the Federal Energy Regulatory Commission at *FercOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY (202) 502–8659.

Any questions regarding the proposed project should be directed to Estela D. Lozano, Director, Regulatory, Rio Bravo Pipeline Company, LLC, P.O. Box 1642, Houston, Texas 77251–1642, by phone at (713) 627–4522 or by email at *estela.lozano@enbridge.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify Federal and State agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

[1] 18 CFR (Code of Federal Regulations) 157.9.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on August 22, 2023. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor. To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before August 22, 2023.

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP23–519–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number CP23–519–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses,

municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [7] and the regulations under the NGA [8] by the intervention deadline for the project, which is August 22, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP23–519–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP23–519–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email at: Estela D. Lozano, Director, Regulatory, Rio Bravo Pipeline Company, LLC, P.O. Box 1642, Houston, Texas 77251–1642, by phone at (713) 627–4522 or by email at *estela.lozano@enbridge.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on August 22, 2023.

Dated: August 1, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–16778 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2561–057]

Sho-Me Power Electric Cooperative; Notice of Application for Surrender of License Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Surrender of license.

b. *Project No:* P–2561–057.

c. *Date Filed:* June 29, 2023.

d. *Applicant:* Sho-Me Power Electric Cooperative.

e. *Name of Project:* Nianqua Hydroelectric Project.

f. *Location:* The project is located on the Nianqua River in Camden County, Missouri.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Peter J. Dawson, Chief Compliance Officer, 417–859–2615, *pdawson@shomepower.com.*

i. *FERC Contact:* Rebecca Martin, (202) 502–6012, *Rebecca.martin@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* August 31, 2023.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory

Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–2561–057. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* On December 3, 2021, the licensee determined it no longer wanted to pursue relicensing of the project and no responses were received on the Commission's December 21, 2021, notice soliciting notices of intent and pre-application documents from other potential applicants. On June 29, 2023, the licensee filed an application to surrender the license. The licensee proposes to leave the facilities in place, including the project dam, power tunnel, powerhouse, and associated facilities. The power canal would be drained and sealed at both ends and the project would be disconnected from the power grid. No ground disturbing activities are proposed with surrender of the project license.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

p. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–16776 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas and Oil Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–921–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Tennessee Gas Pipeline Company, L.L.C's Producer Certified Gas Informational Report for the 12-month period ending June 30, 2023.
Filed Date: 7/31/23.
Accession Number: 20230731–5152.
Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–932–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: Fuel _ LU Quarterly Update Filing Eff Sep 2023 to be effective 9/1/2023.
Filed Date: 7/31/23.
Accession Number: 20230731–5110.
Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–933–000.
Applicants: Ruby Pipeline, L.L.C.
Description: § 4(d) Rate Filing: RP 2023–07–31 FL&U and EPC Rate Adjustment to be effective 9/1/2023.
Filed Date: 7/31/23.
Accession Number: 20230731–5126.
Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–934–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Rate Schedule S–2 Tracker Filing eff 8/1/2023 to be effective 8/1/2023.
Filed Date: 7/31/23.
Accession Number: 20230731–5148.
Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–935–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement—La Frontera #156044 to be effective 8/1/2023.
Filed Date: 7/31/23.
Accession Number: 20230731–5155.
Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–936–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Aug 2023 to be effective 8/1/2023.
Filed Date: 7/31/23.
Accession Number: 20230731–5163.
Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–937–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: REX 2023–07–31 Negotiated Rate Agreement to be effective 8/1/2023.
Filed Date: 7/31/23.
Accession Number: 20230731–5212.
Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–938–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Non-Conforming Agreements Filing (UNS 2023) to be effective 9/1/2023.

Filed Date: 7/31/23.

Accession Number: 20230731–5225.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–939–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—8/1/2023 to be effective 8/1/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5001.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–940–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Osaka 46429 to Texla 56433) to be effective 8/1/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5011.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–941–000.

Applicants: Gulf Run Transmission, LLC.

Description: § 4(d) Rate Filing: Interim Transporter's Use Filing—Effective 9–1–2023 to be effective 9/1/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5023.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–942–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 8–1–23 to be effective 8/1/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5028.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–943–000.

Applicants: UGI Storage Company.

Description: Annual Report of Operational Purchases and Sales of UGI Storage Company.

Filed Date: 8/1/23.

Accession Number: 20230801–5062.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–944–000.

Applicants: Alliance Pipeline L.P.

Description: § 4(d) Rate Filing: Negotiated Rates—Various Aug 1 2023 Releases to be effective 8/1/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5060.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–945–000.

Applicants: Rover Pipeline LLC.

Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements 8–1–23 to be effective 8/1/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5069.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–946–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Non-Conforming Agreements Filing (Tenaska 2023) to be effective 9/1/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5078.

Comment Date: 5 p.m. ET 8/14/23.

Docket Numbers: RP23–947–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Hartree TSA 610670 Aug 2023) to be effective 8/2/2023.

Filed Date: 8/1/23.

Accession Number: 20230801–5080.

Comment Date: 5 p.m. ET 8/14/23.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP23–377–003.

Applicants: WBI Energy Transmission, Inc.

Description: Compliance filing: 2023 Motion Filing to be effective 8/1/2023.

Filed Date: 7/31/23.

Accession Number: 20230731–5185.

Comment Date: 5 p.m. ET 8/14/23.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16787 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2520–000]

SR Litchfield, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of SR Litchfield, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2023.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the

Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16784 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2736–046]

Idaho Power Company; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2736–046.

c. *Date Filed:* February 14, 2023.

d. *Applicant:* Idaho Power Company (Idaho Power).

e. *Name of Project:* American Falls Hydroelectric Project (project).

f. *Location:* On the Snake River, in Power County, Idaho, near the City of American Falls, Idaho. The project occupies 7.37 acres of United States lands administered by the U.S. Bureau of Reclamation.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Brett Dumas, Idaho Power Company, P.O. Box 70 (83707), 1221 West Idaho Street, Boise, ID 83702; (208) 388–2915; email at *bdumas@idahopower.com.*

j. *FERC Contact:* Kristen Sinclair at (202) 502–6587, or *kristen.sinclair@ferc.gov.*

k. *Deadline for filing motions to intervene and protests:* September 29, 2023.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: American Falls Hydroelectric Project (P–2736–046).

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. This application has been accepted for filing, but is not ready for environmental analysis at this time.

m. The existing American Falls Hydroelectric Project is located at Reclamation's American Falls Dam and consists of: (1) three 18-foot-diameter, 240-foot-long, steel-lined penstocks, that connect upstream with similar U.S. Bureau of Reclamation's penstocks and the intake works; (2) a reinforced concrete powerhouse containing three 22.5 MW turbines for total installed capacity of 67.5 MW; (3) a 2,300-foot-long, 138-kilovolt (kV) overhead transmission line extending from the powerhouse downstream to the American Falls Switchyard; (4) a tailrace; (5) recreation facilities; and (6) appurtenant facilities. The project generates an annual average of 395,000 megawatt-hours.

The project is operated in a run-of-river mode and generates an estimated average of 40,669 megawatt-hours per year.

Idaho Power is not proposing any changes to the current operations of the project, as project operations are completely dependent on Reclamation's operation of the dam and available flows.

As part of the license application, Idaho Power filed a settlement agreement between itself and the Idaho Department of Fish and Game (IDFG) that resolves issues related to project effects of turbine mortality on trout. As part of the settlement agreement, Idaho Power proposes to increase the poundage of hatchery-reared trout to be stocked by Idaho Power annually from 8,000-pounds to 24,000-pounds, with the size (fish per pound), time of stocking, and location determined by IDFG in consultation with Idaho Power. Before release, IDFG will certify the general health and condition of the fish.

n. A copy of the application is available for review via the internet through the Commission's Home Page (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining

the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

p. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Issue Scoping Document 1 for comments—September 2023

Comments on Scoping Document 1 Due—October 2023

Issue Scoping Document 2 (if necessary)—November 2023

Issue Notice of Ready for Environmental Analysis—December 2023

Dated: July 31, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–16746 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
1. CP21–57–000, CP16–10–000, CP19–477–000	7–18–2023	FERC Staff.[1]
2. CP21–57–000, CP16–10–000, CP19–477–000	7–20–2023	FERC Staff.[2]
3. CP21–57–000, CP16–10–000, CP19–477–000	7–20–2023	FERC Staff.[3]
4. CP21–57–000, CP16–10–000, CP19–477–000	7–20–2023	FERC Staff.[4]
5. CP22–2–000	7–26–2023	FERC Staff.[5]
6. CP22–2–000	7–26–2023	FERC Staff.[6]
7. CP22–2–000	7–27–2023	FERC Staff.[7]
8. CP22–2–000	7–27–2023	FERC Staff.[8]
9. CP22–2–000	7–31–2023	FERC Staff.[9]
10. CP22–2–000	7–31–2023	FERC Staff.[10]
Exempt:		
1. CP19–14–000	7–24–2023	North Carolina Governor Roy Cooper.
2. CP22–2–000	7–26–2023	U.S. Congress.[11]

[1] Emailed comments dated 7/18/23 from Virginia Feldman.
[2] Emailed comments dated 7/19/23 from Bretton C. Little.
[3] Emailed comments dated 7/20/23 from Margaret Bell.
[4] Emailed comments dated 7/20/23 from Cindy Capra.
[5] Emailed comments dated 7/25/23, et al. from Alessandro Solbiati, and 11 other individual.
[6] Emailed comments dated 7/26/23 from Teresa A. Hennessy, and 10 other individuals.
[7] Comments dated 7/26/23 received from Columbia Riverkeeper and 27 others.
[8] Emailed comments dated 7/26/23 from Alan Unell and 19 other individuals.
[9] Emailed comments dated 7/27/23 from Sandy Polishuk.
[10] Emailed comments dated 7/27/23 from Cynthia Broten.
[11] Senators Jeffrey A Merkley and Ron Wyden.

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16779 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15038–001]

Let It Go, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for an exemption from licensing for the Jefferson Mill Hydroelectric Project, to be located on the Hardware River near the Town of Scottsville, Albemarle County, Virginia, and has prepared an Environmental Assessment (EA) for the project.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that issuing an exemption for the project, with appropriate environmental protective measures, would not constitute a major Federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filings. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15038–001.

For further information, contact Andy Bernick at (202) 502–8660 or by email at *andrew.bernick@ferc.gov.*

Dated: July 31, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–16708 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1276–016; ER10–1287–015; ER10–1292–014; ER10–1303–014; ER10–1319–016; ER10–1353–016; ER18–1150–010; ER18–1183–007; ER18–1184–007; ER22–2187–003; ER22–2188–004; ER23–1411–001.

Applicants: Newport Solar LLC, Northwest Ohio IA, LLC, Northwest Ohio Solar, LLC, Delta Solar Power II, LLC, Delta Solar Power I, LLC, Trishe Wind Ohio, LLC, Dearborn Industrial Generation, L.L.C., CMS Generation Michigan Power, LLC, Genesee Power Station Limited Partnership, CMS Energy Resource Management Company, Grayling Generation Station Limited Partnership, Consumers Energy Company.

Description: Notice of Change in Status of Consumers Energy Company, et al.

Filed Date: 7/31/23.

Accession Number: 20230731–5259.

Comment Date: 5 p.m. ET 8/21/23.

Docket Numbers: ER11–4589–003.

Applicants: EcoGrove Wind, LLC.

Description: Notice of Change in Status of EcoGrove Wind, LLC.

Filed Date: 7/28/23.

Accession Number: 20230728–5240.

Comment Date: 5 p.m. ET 8/18/23.

Docket Numbers: ER11–4677–026; ER16–1354–016; ER16–1672–022; ER16–1913–014; ER18–772–011; ER18–1771–019; ER18–1978–012.

Applicants: Casa Mesa Wind, LLC, Langdon Renewables, LLC, New Mexico Wind, LLC, River Bend Solar, LLC, Chaves County Solar, LLC, Live Oak Solar, LLC, NextEra Energy Montezuma II Wind, LLC.

Description: Notice of Change in Status of NextEra Energy Montezuma II Wind, LLC, et al.

Filed Date: 7/31/23.

Accession Number: 20230731–5257.

Comment Date: 5 p.m. ET 8/21/23.

Docket Numbers: ER13–738–011; ER11–3097–015; ER10–1186–014; ER20–393–001; ER20–392–001.

Applicants: DTE Stoney Corners Wind Farm, LLC, DTE Garden Wind Farm, LLC, DTE Energy Supply, LLC, DTE Energy Trading, Inc., DTE Electric Company.

Description: Notice of Change in Status of DTE Electric Company, et al.

Filed Date: 7/27/23.

Accession Number: 20230727–5211.

Comment Date: 5 p.m. ET 8/17/23.

Docket Numbers: ER15–2013–016; ER10–2435–023; ER10–2440–015; ER12–2510–013; ER12–2512–013; ER15–2014–010; ER15–2020–010; ER15–2022–009; ER15–2026–009; ER18–2252–005; ER19–481–006.

Applicants: LMBE Project Company LLC, MC Project Company LLC, Susquehanna Nuclear, LLC, Montour, LLC, Talen Montana, LLC, Brunner Island, LLC, H.A. Wagner LLC, Brandon Shores LLC, Dartmouth Power Associates Limited Partnership, Camden Plant Holdings, L.L.C., Talen Energy Marketing, LLC.

Description: Notice of Change in Status of Talen Energy Marketing, LLC, et al.

Filed Date: 7/31/23.

Accession Number: 20230731–5260.

Comment Date: 5 p.m. ET 8/21/23.

Docket Numbers: ER16–1993–002.

Applicants: CleanChoice Energy, Inc.

Description: Notice of Change in Status of CleanChoice Energy, Inc.
Filed Date: 7/31/23.
Accession Number: 20230731–5256.
Comment Date: 5 p.m. ET 8/21/23.
Docket Numbers: ER19–2399–002.
Applicants: Caden Energix Hickory LLC.
Description: Notice of Non-Material Change in Status of Caden Energix Hickory LLC.
Filed Date: 7/31/23.
Accession Number: 20230731–5254.
Comment Date: 5 p.m. ET 8/21/23.
Docket Numbers: ER21–2535–001.
Applicants: Dichotomy Power Maine, LLC.
Description: Notice of Non-Material Change in Status of Dichotomy Power Maine, LLC.
Filed Date: 7/31/23.
Accession Number: 20230731–5251.
Comment Date: 5 p.m. ET 8/21/23.
Docket Numbers: ER22–14–001.
Applicants: Darby Solar, LLC.
Description: Notice of Non-Material Change in Status of Darby Solar, LLC.
Filed Date: 7/31/23.
Accession Number: 20230731–5252.
Comment Date: 5 p.m. ET 8/21/23.
Docket Numbers: ER22–1703–004; ER17–2011–002.
Applicants: Castleton Commodities Merchant Trading L.P., Salem Harbor Power Development LP.
Description: Notice of Change in Status of Salem Harbor Power Development LP, et al.
Filed Date: 7/28/23.
Accession Number: 20230728–5239.
Comment Date: 5 p.m. ET 8/18/23.
Docket Numbers: ER22–1928–002; ER22–1945–002.
Applicants: Bracewell LLP, Powells Creek Farm Solar, LLC, Bracewell LLP, Salt City Solar LLC.
Description: Notice of Change in Status of Salt City Solar LLC, et al.
Filed Date: 7/28/23.
Accession Number: 20230728–5237.
Comment Date: 5 p.m. ET 8/18/23.
Docket Numbers: ER22–2116–003; ER22–2115–003.
Applicants: Timber Road Solar Park LLC, Blue Harvest Solar Park LLC.
Description: Notice of Non-Material Change in Status of Blue Harvest Solar Park LLC, et al.
Filed Date: 7/31/23.
Accession Number: 20230731–5253.
Comment Date: 5 p.m. ET 8/21/23.
Docket Numbers: ER22–2116–004; ER22–2115–004.
Applicants: Timber Road Solar Park LLC, Blue Harvest Solar Park LLC.
Description: Notice of Non-Material Change in Status of Blue Harvest Solar Park LLC, et al.
Filed Date: 7/31/23.
Accession Number: 20230731–5261.
Comment Date: 5 p.m. ET 8/21/23.
Docket Numbers: ER23–884–001.
Applicants: Sonoran Solar Energy, LLC.
Description: Notice of Change in Status of Sonoran Solar Energy, LLC.
Filed Date: 7/31/23.
Accession Number: 20230731–5255.
Comment Date: 5 p.m. ET 8/21/23.
Docket Numbers: ER23–937–001.
Applicants: Chevelon Butte RE LLC.
Description: Notice of Change in Status of Chevelon Butte RE LLC.
Filed Date: 7/28/23.
Accession Number: 20230728–5234.
Comment Date: 5 p.m. ET 8/18/23.
Docket Numbers: ER23–2079–001.
Applicants: Kentucky Utilities Company.
Description: Tariff Amendment: KU Errata to Concurrence to the Amenda JRCA to be effective 8/6/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5175.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2385–000.
Applicants: ConocoPhillips Company.
Description: ConocoPhillips Company submits 2022 WECC Soft Price Cap Justification Filing.
Filed Date: 7/7/23.
Accession Number: 20230707–5272.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2533–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: § 205(d) Rate Filing: PASNY RY1 8–2023 to be effective 8/1/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5047.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2534–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2023–08–01_SA 3473 Ameren IL-Hickory Point Solar Energy 2nd Rev GIA (J815) to be effective 7/26/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5057.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2535–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: § 205(d) Rate Filing: WDS RY1 8–2023 to be effective 8/1/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5061.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2536–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Revisions to Attachment AE Sections 8.5.9 and 8.6.5 to be effective 10/1/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5079.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2537–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2023–08–01 Energy Storage Enhancements—Phase 2 to be effective 12/31/9998.
Filed Date: 8/1/23.
Accession Number: 20230801–5092.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2538–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: Tariff Amendment: Notice of Cancellation of Rate Schedule FERC No. 129 to be effective 7/2/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5112.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2539–000.
Applicants: Midcontinent Independent System Operator, Inc., Indianapolis Power & Light Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2023–08–01_SA 4145 AES–WVPA MTIA to be effective 8/1/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5115.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2540–000.
Applicants: Energy Prepay II, LLC.
Description: Baseline eTariff Filing: Baseline new to be effective 8/2/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5148.
Comment Date: 5 p.m. ET 8/22/23.
Docket Numbers: ER23–2541–000.
Applicants: Nevada Cogeneration Associates #2.
Description: Baseline eTariff Filing: Baseline new to be effective 10/1/2023.
Filed Date: 8/1/23.
Accession Number: 20230801–5168.
Comment Date: 5 p.m. ET 8/22/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes.For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 1, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–16788 Filed 8–4–23; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Thursday, August 10, 2023 at 10:30 a.m.

PLACE: Hybrid meeting: 1050 First Street NE, Washington, DC (12th floor) and virtual.

Note: For those attending the meeting in person, current COVID–19 safety protocols for visitors, which are based on the CDC COVID–19 hospital admission level in WASHINGTON, DC, will be updated on the Commission's contact page by the Monday before the meeting. See the contact page at *https://www.fec.gov/contact/.* If you would like to virtually access the meeting, see the instructions below.

STATUS: this meeting will be open to the public, subject to the above-referenced guidance regarding the COVID–19 hospital admission level and corresponding health and safety procedures. To access the meeting virtually, go to the Commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

REG 2023–02 (Use of Artificial Intelligence in Campaign Ads): Draft Notification of Availability

Proposed Final Audit Report on Communications Workers of America—COPE Political Contributions Committee (A21–09)

Audit Division Recommendation Memorandum on Steve Daines for Montana (A21–04)

Audit Division Recommendation Memorandum on Citizens for Waters (A21–01)

Draft Advisory Opinion 2023–05: Alamo PAC

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2023–16920 Filed 8–3–23; 11:15 a.m.]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 22, 2023.

A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *William B. Gray, West York, Illinois; Carol R. Gray, Kimberly A. Gray, Andrew B. Gray, Christina L. Callaway, Bruce W. Callaway, and Brooke N. Callaway, all of Hutsonville, Illinois; George J. Abel, Bridgeport, Illinois; and Blake A. Callaway, Robinson, Illinois;* as the Gray Family group, a group acting concert, to retain voting shares of Hutsonville Banc Corp., and thereby indirectly retain voting shares of Farmers & Merchants Bank of Hutsonville, both of Hutsonville, Illinois.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2023–16821 Filed 8–4–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–23–0060]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled Environmental Health and Land Reuse Certificate Training (formerly ''Assessment of Environmental Health and Land Reuse Certification Training'') to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on April 7, 2023, to obtain comments from the public and affected agencies. ATSDR received no comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Environmental Health and Land Reuse Certificate Training (OMB Control No. 0923–0060)—Reinstatement with Change—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for a Reinstatement with Change information collection request (ICR) titled Environmental Health and Land Reuse Certificate Training (formerly Assessment of Environmental Health and Land Reuse Certification Training) (OMB Control No. 0923–0060).

This certificate program is a collaboration between ATSDR and the National Environmental Health Association (NEHA) under a cooperative agreement. ATSDR and NEHA have a long-standing partnership to build capacity among environmental professionals. The EHLR certification is geared toward NEHA members and ATSDR stakeholders who are environmental professionals, primarily local and state health agency employees but also planners, environmental consultants, environmental non-profits, and students in environmental science, environmental/public health, and planning. The certification goals and course objectives are:

- To increase participant awareness and knowledge of environmental health and land reuse;
- To increase skills and capacity of participants to engage in environmental health and land reuse work; and
- To assess participant feedback and assessment of their own increased awareness, skills, and knowledge in environmental health and land reuse.

Due to the prevalence of potentially contaminated land reuse sites such as brownfields, the certificate program and training modules focus on increasing skills in land reuse and redevelopment through the integration of epidemiology, risk assessment, risk communication, and toxicology concepts and resources.

The Environmental Health and Land Reuse (EHLR) certificate training includes a 5-module ''EHLR Basic'' training. The EHLR Basic certificate is offered in two modes. NEHA independently maintains its non-federally sponsored, asynchronous ''EHLR Basic'' training through its online learning management system (LMS). ATSDR's National Land Reuse Health Program (Land Reuse Program) maintains its classroom version of the training for learners who prefer virtual/classroom instruction or who may have limited broadband.

Under the previous PRA clearance, ATSDR completed a one-time collection of feedback by survey within 6–12 months after participation. This follow-up survey evaluated the subsequent use of the EHLR Basic certificate program training materials and resources to build capacity and skills in environmental health and land reuse work. Under this current Reinstatement with Change ICR, the follow-up survey is no longer needed because the EHLR Basic training course content has been successfully established based on the feedback. In addition, the EHLR Basic training was to be administered under the CDC Training and Continuing Education Online (TCEO) system (see ''Application for Training'' [OMB Control No. 0920–0017; Expiration Date 09/30/2025]). ATSDR has moved away from TCEO and will administer its own classroom courses.

Based on its experience in the past 30 months, ATSDR estimates approximately 100 participants per year will attend ''EHLR Basic'' classroom learning. For burden hour estimation, we assume that all participants have completed all modules and self-assessments. In reality, participants who download the ''EHLR Basic'' course and teach it (*e.g.,* in a college or workplace class) or complete it themselves, may complete these modules on a schedule spread over several months or over more than one year.

For the ''EHLR Basic'' course, ATSDR will administer the following self-assessments for each of the five modules: Engaging with Your Community, Evaluating Environmental and Health Risks, Communicating Environmental and Health Risks to the Community, Redesigning with Health in Mind, and Measuring Success. NEHA will assist ATSDR by issuing certificates of completion and continuing education credits.

ATSDR is also planning a new mode of instruction for supplemental ''EHLR Immersion Training'' in three new modules: Community Engagement, Evaluation of Environmental and Health Risks, and Communicating Environmental and Health Risks. This training will be offered as a face-to-face session at environmental conferences to those who have completed the prerequisite EHLR online or classroom certification. Regarding the supplemental immersion training, ATSDR estimates that 125 conference attendees will meet the prerequisite ''EHLR Basic'' certification requirement and will register for the training through the conference portal. They will be asked to complete a voluntary self-assessment for each module. An additional certificate of completion and continuing education credits will be issued by NEHA for each of the three supplemental immersion trainings.

For both ''EHLR Basic'' classroom and ''EHLR Immersion'' conference training, ATSDR estimates a total of 225 registered participants. Some of the registrations will be through conference registration portals and some may be directly with ATSDR. We estimate the time burden per registration will be three minutes. In keeping with Privacy Act requirements, participants will be offered the ability to opt-out of allowing ATSDR to share their names and email addresses with NEHA. Those that opt-out may still take the training but will not receive a completion certificate or continuing education credits. We anticipate this will be a rare event but are still accounting for this possibility.

Participation in this information collection is voluntary. The total time burden is estimated to be 145 hours, which is an increase of 78 hours over the previously approved 67 hours. The addition of registration and self-

assessment forms and the discontinuation of the follow-up survey under the previous ICR, will result in 1,600 annual responses, which is an increase of 1,400 over the previously approved 200 responses for the follow-up survey alone. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Environmental Health Professionals and Affiliates.	EHLR Registration Form (Basic/Immersion) (online)	225	1	3/60
	EHLR Privacy Act Opt-Out Form (Basic/Immersion)	11	1	1/60
	EHLR Basic Course Module 1 Self-assessment (online)	100	1	5/60
	EHLR Basic Course Module 2 Self-assessment (online)	100	1	5/60
	EHLR Basic Course Module 3 Self-assessment (online)	100	1	5/60
	EHLR Basic Course Module 4 Self-assessment (online)	100	1	5/60
	EHLR Basic Course Module 5 Self-assessment (online)	100	1	5/60
	EHLR Immersion Module 1 Self-assessment (online)	125	1	15/60
	EHLR Immersion Module 2 Self-assessment (online)	125	1	15/60
	EHLR Immersion Module 3 Self-assessment (online)	125	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–16757 Filed 8–4–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–23HD; Docket No. CDC–2023–0067]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Exposures, Health Effects, and Controls of Chemicals from Thermal Spray Coating. The purpose of the proposed data collection is to conduct a survey of thermal spray coating facilities to better understand work practices and controls related to metals, particles, and gases generated during thermal spray coating and to identify areas for potential intervention.

DATES: CDC must receive written comments on or before October 6, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0067 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Exposures, health effects, and controls of chemicals from thermal spray coating—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Thermal spray coating (TSC) is a surface treatment process that enables

different types of feedstock material to be deposited on to various substrates—metals, metal alloys, ceramics, and plastics. The process involves spraying a liquid or molten metal coating product under pressure onto a surface where it solidifies and forms a solid coating. The coating material can be pure metals, metal alloys, carbides, oxides, ceramics, and ceramic metals in wire or powder form that will not decompose when melted. Although TSC technology has been around for decades, recently it has been refined and optimized to impart new properties and functionalities to the coatings, applied through numerous processes such as flame-, cold-, plasma-, and electric arc-spraying, arising from the different combinations of sources of thermal and kinetic energy, form and composition of the feedstock material and other system configurations. TSC processes are relatively simple to use, economical, and have been applied to almost all industrial sectors such as automotive, aerospace, machine shops, electronics, medical, shipyards, and printing. Important uses include coatings for wear prevention, repair, restoration, thermal insulation/conduction, corrosion/oxidation resistance, seals, and decoration.

TSC is a fast-growing and emerging industry, but generates exposures that are known to be hazardous in other settings. However, effects of TSC processes, quantitative exposures, and subsequent health effects remain mostly unknown because of paucity of epidemiologic and exposure studies. Limited data on exposures of workers engaged in TSC and associated operations and personal communications with industrial hygienists in this industry suggests exposures can greatly exceed the current occupational exposure limits, but the prevalence of respiratory abnormalities including occupational asthma and chronic obstructive pulmonary disease in this population remains unknown. In addition, many workplaces conduct TSC work manually or semi-automatically, and some TSC tasks may not be easily amenable to installation of ventilation controls (*e.g.,* during spray-coating of parts with wide surface area).

The purpose of the proposed data collection is to conduct a survey of thermal spray coating facilities to: (1) better understand work practices and controls related to metals, particles, and gases generated during thermal spray coating; (2) identify areas for potential intervention; and (3) identify thermal spray coating facilities willing to participate in future NIOSH exposure and health research.

The burden hours are estimated based on limited pilot testing conducted internally using the survey instrument and previous pilot testing done using a similar survey instrument. In these pilot tests, the amount of time for instruction review, collection of mock information, and the survey completion was between 10–30 minutes. The median time of 20 minutes was used to estimate annual burden hours. Currently, the total number of thermal spray coating businesses in the United States is unknown. In 2004, the Air Resources Board (ARB) in California Environmental Protection Agency conducted the Thermal Spraying Facility Survey of facilities performing thermal spray coating throughout California and reported 97 companies that potentially used TSC. Based on the California ARB report, we estimated approximately 5,000 thermal spray coating businesses nationwide. CDC requests OMB approval for an estimated 1,667 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Thermal spray coating facility managers/owners.	Survey	5,000	1	20/60	1,667
Total					1,667

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–16760 Filed 8–4–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–1015]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''National Electronic Health Records Survey (NEHRS)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 19, 2023 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and

instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Electronic Health Records Survey (NEHRS) (OMB Control No. 0920–1015)—Reinstatement—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for Health Statistics (NCHS) requests a Reinstatement of a previously approved collection titled the National Electronic Health Records Survey (NEHRS) for a three-year clearance. NCHS is requesting approval to collect data for 2024, 2025, and 2026 NEHRS cohorts. NEHRS is a national survey of office-based physicians conducted by NCHS, Centers for Disease Control and Prevention (CDC). NEHRS is sponsored by the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS). The survey is conducted under the authority of Section 306 of the Public Health Service Act (42 U.S.C. 242k).

Although there are other surveys that collect information from United States office-based physicians, NEHRS is unique in that it provides nationally representative information about the use of electronic health records (EHR) and other health information technologies. Additional justifications for conducting future rounds of NEHRS include the need for more complete data to study: (1) documentation of social needs; (2) trends in interoperability; (3) the exchange of patient health information with public health agencies; and (4) the use of telemedicine technology. The new data collections will reestablish trends of patient health information exchange with public health agencies, telemedicine technology use, as well as the evolving engagement in interoperability; particularly with respect to electronically sending, receiving, integrating, and searching for patient health information through these systems. Improving interoperability of electronic health information is a major priority for ONC, and NEHRS can provide ONC with data on physicians' experience with interoperability.

CDC requests OMB approval for an estimated 5,544 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Office-based physicians or office staff	NEHRS	16,633	1	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–16758 Filed 8–4–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–23HC; Docket No. CDC–2023–0066]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Food safety knowledge, attitude, and practices survey of correctional workers. The proposed data collection will create a baseline for the knowledge, attitude, and practices (KAP) of correctional staff working in a variety of U.S. correctional facilities and will assess the overall food safety approaches to training, and the receptiveness of correctional staff to being a part of food safety at their facilities.

DATES: CDC must receive written comments on or before October 6, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0066 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new

proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Food safety knowledge, attitude, and practices survey of correctional workers—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2017, an analysis of Foodborne Disease Outbreak Surveillance System (FDOSS) epidemiology data demonstrated a disproportionately high burden of foodborne outbreaks and outbreak-associated illnesses in correctional facilities compared to other settings. The CDC is implementing training and policy initiatives to reduce foodborne illness in correctional facilities. However, CDC has little understanding of current training and overall food safety culture among individuals working in correctional settings. The proposed survey will allow for the collection of baseline knowledge, attitude, and practices (KAP) of correctional staff working in a variety of U.S. correctional facilities (including Federal, State, Tribal, local and private facilities). The survey will assess overall food safety approaches to training, and the receptiveness of correctional staff to being a part of food safety at their facilities. The information collection request will be open for three years to allow for a follow-up survey to support program evaluation of CDC programmatic and policy initiatives 2–3 years following the initial assessment. There is no legal requirement for CDC to collect this information. However, CDC is the Federal authority on identifying and preventing foodborne illness and as such, is best suited to collect data in support of improved food safety practices at State, local, Federal, and Tribal correctional facilities.

Following the initial baseline data collection, CDC plans to develop food safety best practices which are tailored to the needs and risks of correctional facilities. Best practices will be disseminated via pilot training initiatives through the Integrated Food Safety Centers of Excellence (CoEs) supported by CDC's ELC Cooperative Agreement (CDC RFA CK19–1904). The overall goal of program will be to reduce foodborne illness outbreaks in correctional facilities by increasing training and implementing policy to improve food safety.

CDC requests OMB approval or an estimated 5,000 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Correctional workers	KAP survey of correctional workers, baseline and follow-up assessments.	5,000	2	30/60	5,000
Total					5,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–16759 Filed 8–4–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10393]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of

information technology to minimize the information collection burden.

DATES: Comments must be received by October 6, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10393 Beneficiary and Family Centered Data Collection

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Beneficiary and Family Centered Data Collection; *Use:* To ensure the QIOs are effectively meeting their goals, CMS collects information about beneficiary experience receiving support from the QIOs. This is a request to revise the information collection. The revisions to this information collection include the deletion of the previously approved Direct Feedback Survey and associated instructions and the General Feedback Web Survey and associated instructions. The information collection uses both qualitative and quantitative strategies to ensure CMS and the QIOs understand beneficiary experiences through all interactions with the QIO including initial contact, interim interactions, and case closure. Information collection instruments are tailored to reflect the steps in each type of process, as well as the average time it takes to complete each process. The information collection will:

- Allow beneficiaries to directly provide feedback about the services they receive under the QIO program;
- Provide quality improvement data for QIOs to improve the quality of service delivered to Medicare beneficiaries; and
- Provide evaluation metrics for CMS to use in assessing performance of QIO contractors.

To achieve the above goals, information collection will include: Experience Survey: The Experience Survey will be administered via telephone and mail to beneficiaries/representatives after the Quality of Care (Medical Record Review) complaint/Immediate Advocacy/appeal case has been closed. The goal of the Experience Survey is to assess beneficiary overall and specific experiences with the BFCC QIOs. *Form Number:* CMS–10393 (OMB control number: 0938–1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 9,000; *Number of Responses:* 9,000; *Total Annual Hours:* 2,250. (For policy questions regarding this collection, contact Renee Graves-Dorsey at 410–786–7142.)

Dated: August 2, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–16793 Filed 8–4–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Medical Assessment Form and Dental Assessment Form (Office of Management and Budget 0970–0466)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the forms Medical Assessment Form (formerly, the Initial Medical Exam (IME) Form and Supplemental Tuberculosis (TB) Screening Form) and Dental Assessment Form (formerly, the Dental Exam Form) (Office of Management and Budget (OMB) #0970–0466, expiration December 31, 2023). Changes are proposed to the currently approved forms.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION: The ACF ORR places unaccompanied children in their custody in care provider programs until unification with a qualified sponsor. Care provider programs are

required to provide children with a range of services including medical, dental, and mental health care. Each child must receive an initial medical exam (IME) within 2 business days of admission to an ORR care provider program or temporary influx care facility. The IME satisfies *Flores* requirements which require a ''complete medical examination, including a screening for infectious disease''. The purposes of the IME are to assess general health, administer vaccinations in keeping with U.S. standards (also required by *Flores*), identify health conditions that require further attention, and detect contagious diseases of public health importance, such as influenza or TB. The IME is performed by a licensed health care provider and comprised of a complete medical history and physical exam, risk, and age-based laboratory screenings, TB screenings and immunizations. In addition, children may be referred to a specialist by their healthcare provider for acute or chronic conditions that require additional evaluation. If a child is in ORR custody 60 to 90 days after admission, they must receive an initial dental exam, or sooner if directed by state licensing requirements. Children who are in ORR care for an extended length of time may require urgent or routine medical and dental well-child evaluations.

The forms are used as worksheets for generalist healthcare providers and pediatric and other medical specialty healthcare providers to compile information that would otherwise have been collected during the health evaluation. Once completed, the forms are given to care provider program staff for entry into ORR's secure, electronic data record system. Data is used to monitor the health of unaccompanied children while in ORR care, for case management of any identified illnesses/conditions and to ensure care provider program compliance with ORR requirements.

ORR has merged the former IME Form and Supplemental TB Screening Form into one form, the Medical Assessment Form which will be used during all medical evaluations with a mid-level or higher medical professional. ORR has incorporated other changes to the forms to streamline the flow of data collection, clarify the intent of certain fields, improve data quality, and ensure alignment with ORR requirements. In addition, ORR has written instructional letters for the Medical Assessment Form and Dental Assessment Form to explain the purpose of the forms and provide general guidance on completion to healthcare providers.

Respondents: Healthcare providers (pediatricians, medical specialists, and dentists), Care Provider Program Staff.

Annual Burden Estimates

ESTIMATED OPPORTUNITY TIME FOR RESPONDENTS

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Medical Assessment Form	Pediatricians, General	300	840	0.22	55,440
	Medical specialist, General	750	22	0.22	3,630
Dental Assessment Form	Dentists	250	64	0.12	1,920

Estimated Total Annual Burden Hours: 60,990.

ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Medical Assessment Form completed by a medical professional.	Care Provider Program Staff	500	537	0.33	88,605
Medical Assessment Form not completed by a medical professional (information obtained via health records).		500	100	0.17	8,500
Dental Assessment Form		500	32	0.17	2,720

Estimated Total Annual Burden Hours: 99,825.

Authority: 6 U.S.C. 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (Jenny Lisette Flores, et al., v. Janet Reno, Attorney General of the United States, et al., Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–16822 Filed 8–4–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Release of Unaccompanied Children From Office of Refugee Resettlement Custody (Office of Management and Budget #0970–0552)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is inviting public comments on revisions to an approved information collection. The request consists of several forms that allow the Unaccompanied Children (UC) Program to process release of unaccompanied

children from ORR custody and provide services after release.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to ACF, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR is proposing revisions to four forms (Forms R–1, R–2, R–4, and R–6), the addition of one new form (Form R–9), removal of one form (Form R–3), and continued use of the current versions of three forms (Forms R–2, R–4, and R–6). See below for a detailed description of the proposed revisions for each instrument.

Verification of Release (Form R–1)

There are two currently approved versions of this form under this information collection—one for UC Portal and one for UC Path. ORR proposes discontinuing the UC Portal version, incorporating the UC Path version into the UC Portal system, and making the below-listed revisions.

ORR also updated the burden estimates for this form to account for an increase in the number care provider facilities and in the number of children placed in ORR care. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent increased from 253 to 428.

Proposed Revisions

- Child's Information
  - Retitle section from *Minor's Information* to *Child's Information.*
  - Remove the term ''minor'' from the *Name, Date of Birth,* and *A#* fields.
  - Remove the *Height, Weight,* and *Hair Color* fields. ORR determined that these fields are not a good fit for this form given that height and weight will change quickly as the child grows and hair color is often altered.
  - Add fields for *Preferred Language* and *Country of Birth.* These fields will be auto-populated.
- Sponsor Information
  - Rephrase *Name of Sponsor* to *Name.*
  - Rephrase *Telephone #* to *Primary Phone #.*
  - Remove *Alias (if any)* field.
- Acknowledgement of the Sponsor Care Agreement
  - Rephrase *Name of ORR Care Provider* to *ORR Care Provider Name.*
  - Rephrase *Date* to *Discharge Date.*

Discharge Notification (Form R–2)

There are two currently approved versions of this form under this information collection—one for UC Portal and one for UC Path. ORR proposes the below-listed revisions to the current UC Portal version and plans to discontinue the UC Path version.

In addition, ORR is requesting continued use of the current UC Portal version of this instrument to support a phased rollout of improvements to the UC Portal system.

ORR also updated the burden estimates for this form to reflect the revisions and to account for an increase in the number of care provider facilities and in the number of children placed in ORR care. The annual number of respondents increased from 216 to 300; the annual number of responses per respondent increased from 290 to 487; and the average burden hours per response increased from 0.17 to 0.25.

Proposed Revisions

- UC Basic Information
  - Remove *Age* field and add *Portal ID* field (auto-populated system-generated number).
- Discharge Basic Information
  - Retitle section from *Discharge Notification* to *Discharge Basic Information.*
  - Update the dropdown options for the *Discharge Type* field to be inclusive of all types of discharge scenarios and add an *If Other, specify* text box field.
  - Add the following fields from the UC Path version:
    - *Status*
    - *Scheduled Date of Discharge* (rephrase from *Release Scheduled Date/Time*)
    - *Discharge Delay* (also expand dropdown options and add an *If Other, specify* text box field)
    - *UC Parent Name*
    - *Parent/Legal Guardian Separation*
    - *MPP Case*
    - *Next Immigration Hearing Date*
  - Add the following new fields:
    - *UC Parent Discharge Type*
    - *UC Parent A#*
    - *Did the medical coordinator certify that the child is medically fit to travel?*
  - Move the field *Legal Status of Child* (rephrase from *Legal Status of Minor*) under this section and add an *If Other, specify* text box field.
- Discharge Details
  - Retitle section from *ORR Decision from Latest Release Request* to *Discharge Details.*
  - Employ progressive disclosure for this section so that only fields relevant to the selected *Discharge Type* (and where applicable *UC Parent Discharge Type*) are displayed.
  - Rephase field label to *Receiving Program Name* (currently *Program Minor was Transferred to*).
  - Remove the following fields:
    - *DHS Family Shelter*
    - *Local Law Enforcement*
  - Add the following fields from the UC Path version:
    - *Government Agency Name* (rephrase from *Name of Government Agency*)
    - *Government Agency Type* (rephrase from *Government Agency* and update dropdown options to add *ICE ERO* and remove *State/Local Facility*)
    - *Date Granted Voluntary Departure*
    - *Date Travel Document Requested*
    - *Date Travel Document Issued*
    - *Referral to Services in Country of Origin* (update dropdown options to rephrase *KIND (Kids in Need of Defense)* to *KIND CMRRP* and add *Other Services*)
    - *Completed Referral to Services in Country of Origin*
    - *DHS Age Out/Age Redetermination Plan* (rephrase from *DHS Age Out Plan*)
  - Add the following new fields:
    - *Type of Post–18 Discharge Plan*
    - *Discharged into Custody of*
    - *UC Parent Discharged into Custody of*
- Transportation Details
  - Transfer this section and all fields contained within from the UC Path version without further revisions.

ORR Release Notification—ORR Notification to Immigration and Customs Enforcement (ICE) Chief Counsel—Release of Unaccompanied Child to Sponsor and Request To Change Address (Form R–3)

ORR proposes removing this instrument from the information collection. No information is requested specifically for this auto-populated document, instead this a document that is auto-populated with information ORR collects in other Office of Management

and Budget (OMB)-approved forms. The use of information consolidated on this notification document is consistent with the purpose for which ORR originally collects the information in its other forms and with ORR's system of records notice (81 FR 46682). This form simply compiles and presents approved information collections in a different format and is therefore not subject to the PRA.

The fields in this form are auto-populated from the following instruments:

- Discharge Notification (Form R–2, approved under this information collection)
- Release Request (Form R–4, approved under this information collection)
- Sponsor Assessment (Form S–5) (approved under OMB# 0970–0553)
- Care provider program user profile (not subject to PRA per OMB's April 7, 2010 memorandum *Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act*)

Release Request (Form R–4)

There are two currently approved versions of this form under this information collection—one for UC Portal and one for UC Path. ORR proposes the below-listed revisions to the current UC Portal version and plans to discontinue the UC Path version.

In addition, ORR is requesting continued use of the current UC Portal version of this instrument to support a phased rollout of improvements to the UC Portal system.

ORR also updated the burden estimates for this form to reflect the revisions and to account for an increase in the number of care provider facilities and in the number of children placed in ORR care. The annual number of respondents increased from 216 to 300 for care providers; the annual number of responses per respondent increased from 254 to 430 for care providers and 321 to 756 for case coordinators; and the average burden hours per response increased from 0.42 to 0.58 for care providers and 0.33 to 0.50 for case coordinators.

Proposed Revisions

- Case Details—Retitle section from *UC Basic Information* to *Case Details.*
- Release Request Details
  - Replace the current *Requester Information* section with this section.
  - Auto-populate all fields in this section based on information captured in other sections of the form, information collected in the Sponsor Assessment (Form S–5, approved under OMB# 0970–0553), and system user information.
  - Add the following new fields: *Case Category, Relationship, Process,* and *Release Status.*
  - Replace the fields *Requester Name* and *Requester Title* with the following auto-populated fields: *Case Manager Name, Case Coordinator Name, Local Federal Field Staff Name,* and *Box Federal Field Staff Name (if Applicable).*
- Sponsor Information
  - Add the following new fields that will auto-populate based on information entered in the Sponsor Assessment (Form S–5, approved under OMB# 0970–0553): *Evidence gathered to support sponsor/child relationship, Birth Certificate Trail, Concurrent and Prior Sponsorships, Sponsor's Previous Address(es), Sponsor's Current Address,* and *Flags Associated with Sponsors.*
  - Add the following new fields that will be completed by the user: *Other* (in response to *What evidence has been gathered to support sponsor/child relationship*), *Does sponsor birth certificate match official sponsor ID?, If no, please note discrepancies between sponsor birth certificate and official sponsor ID, Was birth certificate verified by the consulate, If unable to conclusively prove relationship, please explain,* and *Concurrent and Prior Sponsorships Evaluation.*
  - Remove the following fields: *Legal Status, If other Non-Immigrant Visa, Specify, If Other Immigrant Visa, Specify, SSN, Provide Details on Relationship Including Official Documentation, Sponsor Household Occupants,* and *Affidavits of Support.*
- Family Reunification Packet & Supporting Documents
  - Add this new section which will reference all supporting documentation relevant for release recommendations to minimize the amount of cross-referencing system users typically do to complete this form.
  - Unification Documentation Subsection
    - Add the following new fields that will auto-populate based on information enter in the Sponsor Assessment (Form S–5, approved under OMB# 0970–0553): *Sponsor, Sponsor Identification, Was the sponsor address validated through SmartyStreets?, Choose to link google maps and google earth screenshots, What documentation was provided as proof of address, HHM Name, HHM Identification, ID Expiration Date, Alternate Caregiver (ACG) Name, Alternate Caregiver Identification,* and *ID Expiration Date.*
    - Add the following new fields that will be completed by the user: *Date FRP Received by Case Manager, Describe the sponsor's ability to provide housing, food, and education to the child,* O*n what date was the Letter of Designation received, Not Collected (checkbox),* and *On what date was the Legal Orientation Program for Custodians Packet sent to the Sponsor?*
  - Child-Level Events Subsection
    - Hyperlink to information collected in the Child-Level Event (Form A–9, approved under OMB# 0970–0547), when applicable. This section is proposed purely to assist users in having all case information in one place. Child-Level Events in and of themselves are not the sole basis of release decisions but can inform whether a Home Study recommendation is made, what level of post-release services (PRS) is recommended for release, or what type of program would be best suited to a child released to program rather than a sponsor.
  - Legal Representation Subsection
    - Add the following new fields: *Does the child have an attorney of record?* and *Date Attorney Appointed, Is this a Migrant Protection Protocol case?, Is there a removal order for the unaccompanied child?,* and *Is this a Parental/Legal Guardian separation case?*
  - Child Advocate Subsection
    - Add the following new fields: *Does the child have a Child Advocate appointed?, Date Child Advocate Appointed.*
    - Add a hyperlink to the Child Advocate Best Interest Determination (which is uploaded into UC Portal) upon completion, is proposed to be added into this form for the user's ease of reference.
  - OTIP Eligibility Subsection
    - This subsection requests information related to referrals made to the Office of Trafficking in Persons, where applicable.
    - Add the following new fields: *Is the unaccompanied child a material witness?, Outcome of OTIP Referral, OTIP Status, Date of OTIP Referral, Date OTIP Eligibility Begins,* and *Date OTIP Eligibility Expires.*
    - Add a hyperlink to the OTIP Eligibility Letter (if applicable) which is uploaded into UC Portal, upon completion, will be added into this form for the user's ease of reference.

○ Release to Program (URM, State, Local Social Service Agency, Other) Subsection

▪ Add the following new fields: *URM Program Requirement Eligibility, Date the URM Eligibility was Obtained, Program Accepts Guardianship, Program Agreed to Condition of Release, How/Why Program was identified, Date of Referral to the Program, Date of Acceptance, Program Comment,* and *Program License Type*, *Program Type, Facility Name, Program Address,* and *Other.*

▪ Add a hyperlink to the Discharge Plan (Form R–9), which is a new instrument proposed under this request.

• Criminal Investigations

○ Auto-populate information on background check results from the Sponsor Assessment (Form S–5, approved under OMB# 0970–0553).

○ Employ progressive disclosure to limit or expand each subsection based on the facts of the case.

○ Criminal Investigations: Sponsor Subsection

▪ Add the following new fields that will be completed by the user: *Has the sponsor self-disclosed any criminal history? Please Explain., Is there evidence of rehabilitation? Please Explain., FFS requested the following additional information to adjudicate CA/N Results:, FFS adjudicated referred CA/N Check Results, FFS Requested the following information to adjudicate Fingerprints Results:, FFS adjudicated Fingerprints Results,* and *Did the FFS instruct that it is safe to move forward with the sponsor given the Fingerprint and CA/N Results? Please Explain:.*

○ Criminal Investigations: Household Member (HHM) Subsection

▪ Add the following new fields that will be completed by the user: *Has the household member self-disclosed any criminal history? Please Explain., Is there evidence of rehabilitation? Please Explain., FFS requested the following additional information to adjudicate CA/N Results:, FFS adjudicated referred CA/N Check Results, FFS Requested the following information to adjudicate Fingerprints Results:, FFS adjudicated Fingerprints Results,* and *Did the FFS instruct that it is safe to move forward with the sponsor given the HHM's Fingerprint and CA/N Results? Please Explain:*

○ Criminal Investigations: Alternate Caregiver (ACG) Subsection

▪ Add the following new fields that will be completed by the user: *Has the alternate caregiver self-disclosed any criminal history? Please Explain., Is there evidence of rehabilitation? Please Explain., FFS requested the following additional information to adjudicate CA/N Results:, FFS adjudicated referred CA/N Check Results, FFS Requested the following information to adjudicate Fingerprints Results:, FFS adjudicated Fingerprints Results,* and *Did the FFS instruct that it is safe to move forward with the sponsor given the alternate caregiver's Fingerprint and CA/N Results? Please Explain:*

• Home Study Recommendation Section

○ Move all fields related to home study recommendations into this new section. Currently, the Case Manager Recommendation, Case Coordinator Recommendation, and ORR Decision sections contain fields related to home study recommendations, release recommendations, and cancellation reasons. Moving fields related to home study recommendations here will distinguish the home study decision from the release decision and cancellation reasons. This section will contain subsections for each party involved in the home study recommendation and decision process—Case Manager Recommendation, Case Coordinator Recommendation, and ORR Decision.

○ Add a new dropdown option, *Do Not Recommend Home Study,* to the case manager and case coordination recommendation fields and the decision field (current dropdown options are *Home Study—TVPRA, Home Study—Discretionary,* and *Home Study—ORR Mandated*).

○ Add a new field, *Explain your rationale for recommending or not recommending a Home Study,* to all three subsections.

○ Add the following new fields that will appear if a home study is approved: *Date Home Study Referral Sent, Date Home Study Referral Accepted,* and *Date Home Study Completed.* These fields will auto-populated based on UC Portal system data.

○ Add a hyperlink to the Home Study Report will appear after it is uploaded into UC Portal, as well as a new field: *Please summarize the results of the home study including any recommendations made by the Home Study provider. If there are any concerns and how they were mitigated.*

• Release Recommendation

○ Bundle the Case Manager Recommendation, Case Coordinator Recommendation, and ORR Decision sections together as subsections under this new section. Fields related to home study recommendations will be moved into the Home Study Recommendation section (as discussed above) and fields related to cancellation reasons will be moved into the Release Cancellation section (as discussed below).

○ Add three checkboxes to assist in routing for this form: *Submitted on Weekend or Holiday?, ICF or Casa Padre?,* and *Certified Medically Fit for Travel* (a field that can only be completed by ORR federal staff).

○ Update the dropdown options for the following fields to reflect that all children released from ORR care will receive PRS beginning January 1, 2024: *Case Manager Release Recommendation, Case Coordinator Release Recommendation,* and *ORR Release Decision.*

○ Add the following fields to direct case routing: *Case Manager Routing, Case Coordinator Routing, ORR Routing (if applicable).*

○ Add the following new fields to each subsection: *Describe case factors that contribute positively to your release recommendation, Describe case factors that contribute negatively to your release recommendation,* and *List all documents used as evidence to support your recommendation to deny release* (will only appear if the recommendation is to deny release).

○ Case Manager Recommendation Subsection

▪ Add checkboxes for the types of documents the user reviewed to inform their recommendation as well as an *Other* text box to describe any documents reviewed that are not included in the checklist.

○ Case Coordinator Recommendation Subsection

▪ Add a new field, *Case Coordinator Pending Information* as well as an *Other* text box to capture addition information is the user selects *Other.*

○ ORR Decision Subsection

▪ Add the following new fields: ORR Decisionmaker Role, *ORR Remand Reason* (along with a corresponding *Other* text field), and *ORR HOLD Reason.*

▪ Add a hyperlink to the final Notification of Denial Letter signed by the ORR Director that will appear if *Deny Release* is selected for a Cat 1, Cat 2A, or Cat 2B sponsor.

• Release Cancellation

○ Move fields related to release cancellation into this new section to distinguish cancellations from home study and release recommendations. This section will contain subsections for

each party involved in cancellations—Case Manager Recommendation, Case Coordinator Recommendation, and ORR Decision.

○ Add the following new fields to each subsection: *Cancellation Reason* and *Describe circumstances of release cancellation.*

○ Add the following fields that will prompt the user to select a more specific reason for cancellation: *Specific Sponsor Withdrawal Reason, Specific Reason for Child Discharge (Non-unification or Program),* and *Specific Administrative Closure Reason.*

Virtual Check-In Questionnaire (Form R–6) (Formerly Titled Safety and Well-Being Call)

There are two currently approved versions of this form under this information collection—one in Excel and one for UC Path. ORR proposes the below-listed revisions to the current UC Path version and plans to incorporate the revised version into the UC Portal system.

In addition, ORR is requesting continued use of the current Excel version of this instrument to support a phased rollout of improvements to the UC Portal system.

ORR updated the burden estimates for this form to reflect form revisions, to account for an increase in the number of care provider facilities and in the number of children placed in ORR care, and to improve burden accuracy. The burden estimate was split into three separate line items for each respondent. The annual number of respondents changed from 216 care providers to 40 PRS providers, 128,487 sponsors, and 128,487 children; the annual number of responses per respondent increased from 253 to 19,273 for PRS providers, 3 for sponsors, and 3 for children; and the average burden hours per response increased from 0.42 to 0.58 for PRS providers, 0.17 to 0.25 for sponsors, and 0.17 to 0.25 for children.

ORR plans to shift responsibility for conducting safety and well-being calls from care provider facilities to PRS providers. Moving forward these calls will be called virtual check-ins. All children released to a sponsor and their sponsors will continue to receive calls, however, the frequency of the calls will increase from one to three calls—conducted at seven business days, 14 business days, and 30 business days after the child's release from ORR custody.

ORR proposes the following revisions to the UC Path version of Form R–6 to support this change in process:

• Change the title to ''Virtual Check-In Questionnaire.''

• Pre-Call Information—This section will replace the UAC Basic Information and Case Information sections. The new section retains the child and sponsor information and adds fields to capture phone numbers for contacts in the care plan and in home country. All information in this section will be auto-populated.

• Questions for the Sponsor—This section will replace the Sponsor Address Confirmation and Sponsor Questions sections. The new section will include subsections for Location & Contact Information, Child's School, Child's Medical & Mental Health, Legal & Child's Immigration, Safety & Well-Being, and Child's Work. This section adds 13 new questions. The section also retains, and in some cases adds additional follow-up questions for, the questions confirming the address, whether the child still lives with the sponsor, whether the child is registered for school, whether the child is having any behavioral or health issues, whether the sponsor has attended the Legal Orientation Program for Custodians of Unaccompanied Children (LOPC) presentation, whether the sponsor is aware of, and notified the child of, the child's next immigration court date, whether the child has attended their scheduled court hearing, whether the sponsor still has the child's *Verification of Release* form, and whether the sponsor has been asked to pay for the release of the child.

• Questions for the Child—This section will replace the UAC Address Confirmation and UAC Questions sections. The new section will include subsections for Location, School, Medical & Mental Health, Legal & Immigration, Safety & Well-Being (Post-Release and In-Care), and Work. The new section adds 31 new questions. The section also retains, and in some cases adds additional follow-up questions for, the questions confirming the address, whether the child still lives with the sponsor, whether the child is attending school, whether the child feels safe, whether the child has been adequately provided for, whether anyone has been asked to pay for the release of the child, whether the child is being forced to work or pay money, and whether the child is aware of their next immigration court date.

• Post-Call Assessment and Outcomes—This section will replace the following sections: Sponsor Interview, UAC Interview, Case Manager Observation and Action Follow-Up, UAC May be in Immediate Danger, UAC May be Unsafe, UAC May Have Been Sexually Abused or Harassed While in ORR Care, Additional Support Services or LOPC Appointment, and Case Manager Certification. The new section adds 6 new questions. The section also retains, and in some cases builds on, questions on whether the phone was disconnected, sponsor participation, whether the child appears to be in immediate danger, whether the child or sponsor should be assessed for additional PRS, post-call actions taken, and reasons for elevation (if applicable).

Discharge Plan (Form R–9)

ORR care providers are required to conduct discharge planning for children who are not likely to be released to a sponsor, may obtain a form of lawful immigration relief, are projected to have a prolonged stay in ORR care, and/or will soon turn age 18 and age out of ORR care. Discharge planning is a participatory process that takes into consideration the wishes and goals of the child and includes consultation with the child's legal services provider, attorney of record, child advocate, and other stakeholders (*e.g.,* parents, legal guardian in home country) as applicable. Case managers engage in concurrent planning, whenever possible, to ensure there are multiple options included in the child's discharge plan.

ORR developed this instrument to improve and standardize the process for discharge planning across its national network of care providers. The new instrument will collect information on the following topics:

- Child's Basic Information
- Placement Information After Release
- UC Program Family Group
- Case Management Needs
- Family Unification Plan
- Education and Career Plan
- Financial Plan
- Residential Plan
- Community Resources Plan
- Legal Services Plan
- Voluntary Departure Plan
- Release to DHS ICE Field Office Juvenile Coordinator Upon Age Out
- Transportation Plan
- Health Discharge Safety Plan
- Behavioral Observations Summary
- Life Skills Summary

The Legal Services Plan section of this instrument will replace Post Legal Status Plan (Form L–8), which is currently approved under OMB# 0970–0565. ORR plans to submit a nonsubstantive change request to discontinue Form L–8 soon.

Respondents: ORR grantee and contractor staff; and released children and sponsors.

ANNUAL BURDEN ESTIMATES

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Verification of Release (Form R–1)	300	428	0.17	21,828
Discharge Notification (Form R–2)	300	487	0.25	36,525
ORR Release Notification—ORR Notification to ICE Chief Counsel Release of UC to Sponsor and Request to Change Address (Form R–3)	300	440	0.08	10,560
Release Request (Form R–4)—Care Provider	300	430	0.58	74,820
Release Request (Form R–4)—Case Coordinator	170	756	0.50	64,260
Virtual Check-In Questionnaire (R–6)—Sponsor	128,487	3	0.25	96,365
Virtual Check-In Questionnaire (R–6)—Child	128,487	3	0.25	96,365
Virtual Check-In Questionnaire (R–6)—PRS Provider	40	19,273	0.58	447,134
Discharge Plan (Form R–9)	300	11	2.00	6,600

Estimated Annual Burden Hours Total: 854,457.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno* Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–16795 Filed 8–4–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Mental Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (Office of Management and Budget 0970–0509)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Mental Health Assessment Form (formerly the Health Assessment Form) and Public Health Investigation Forms, Active Tuberculosis (TB) and Non-TB Illness (Office of Management and Budget (OMB) #0970–0509, expiration December 31, 2023). Changes are proposed to the currently approved forms.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION: The ACF Office of Refugee Resettlement (ORR) places unaccompanied children in their custody in care provider programs until unification with a qualified sponsor. Care provider programs are required to provide children with a range of services including medical, dental, and mental health care. While in ORR care, children meet with onsite mental health counselors on a regular basis. If a child is identified as potentially having a more serious mental health condition, they are referred to a psychiatrist, psychiatric nurse practitioner or physician's assistant, licensed psychologist, or any other community-based licensed mental health provider (*e.g.,* social worker).

The Mental Health Assessment form is used as a worksheet for mental health specialists to compile information that would otherwise have been collected during the evaluation. Once completed, the form is given to care provider program staff for entry into ORR's secure, electronic data record system. Data is used to monitor the health of unaccompanied children while in ORR care and for case management of any identified conditions.

Children may be exposed to nationally reportable infectious diseases during the journey to the U.S., while in the custody of the Customs and Border Protection after crossing the border, or during their stay in ORR custody. Public health interventions such as quarantine, vaccination or lab testing may be initiated to reduce possible disease transmission. Following an exposure, children are assessed onsite by care provider program staff and if found to be symptomatic, referred to a healthcare provider for evaluation.

The Public Health Investigation Forms are used as worksheets by care provider program staff to record their findings when an exposure has been reported. Once completed, they will enter the data into ORR's secure data record system. Data is used to track disease transmission and health outcomes of children in ORR care.

ORR has repurposed the former Health Assessment Form from a medical and mental health information collection to a mental health collection only, and renamed it, the Mental Health Assessment Form. ORR has incorporated other changes to the forms to streamline the flow of data collection, clarify the intent of certain fields, improve data quality, and ensure alignment with ORR requirements. In

addition, ORR has written an instructional letter for the Mental Health Assessment Form to explain the purpose of the form and provide general guidance on completion to healthcare providers.

Respondents: Mental health professionals (psychiatrists, psychiatric nurse practitioners or physician's assistants, licensed psychologist or any other community based licensed mental health provider (*e.g.,* social worker)), care provider program staff.

Annual Burden Estimates

ESTIMATED OPPORTUNITY TIME FOR RESPONDENTS

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Mental Health Assessment Form	Mental health professionals	500	6.8	0.18	612
Public Health Investigation Form: Active TB.	Care provider program staff	500	1	0.08	400
Public Health Investigation Form: Non-TB Illness.		500	200	0.08	8,000

Estimated Total Annual Burden Hours: 9,012.

ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Mental Health Assessment Form	Care provider program staff	500	6.8	0.21	714
Public Health Investigation Form: Active TB		500	1	0.08	400
Public Health Investigation Form: Non-TB Illness		500	200	0.08	8,000

Estimated Total Annual Burden Hours: 9,114.

Authority: 6 U.S.C. 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–16840 Filed 8–4–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 060

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 060'' (Recognition List Number: 060), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable August 7, 2023.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for

information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 060.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 060.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

An electronic copy of Recognition List Number: 060 is available on the internet at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section IV for electronic access to the searchable database for the current list of FDA-recognized consensus standards, including Recognition List Number: 060 modifications and other standards-related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 060'' to Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301–796–6580. Send one self-addressed adhesive label to assist that office in processing your request, or Fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301–796–6580, *CDRHStandardsStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 of the FD&C Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In the **Federal Register** of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.'' The guidance describes how FDA has implemented its standards recognition program and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.* Modifications to the initial list of recognized standards, as published in the **Federal Register,** can be accessed at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.*

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains on its website HTML and PDF versions of the list of FDA Recognized Consensus Standards, available at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.* Additional information on the Agency's Standards and Conformity Assessment Program is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 060

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA is using the term ''Recognition List Number: 060'' to identify the current modifications.

In table 1, FDA describes the following modifications: (1) the withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 060.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–127	1–161	ISO 16628 Second edition 2022–06 Anaesthetic and respiratory equipment—Tracheobronchial tubes.	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–213	2–299	ASTM F1904–23 Standard Guide for Testing the Biological Responses to Medical Device Particulate Debris and Degradation Products in vivo.	Withdrawn and replaced with newer version.
2–222	2–300	ISO 10993–2 Third edition 2022–11 Biological evaluation of medical devices—Part 2: Animal welfare requirements.	Withdrawn and replaced with newer version.
2–227	2–301	ASTM F1983–23 Standard Practice for Assessment of Selected Tissue Effects of Absorbable Biomaterials for Implant Applications.	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–87	3–184	ASTM F2477–23 Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents and Endovascular Prostheses.	Withdrawn and replaced with newer version.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–86		ANSI/ADA Standard No. 38–2000 (R2015) Metal-Ceramic Dental Restorative Systems.	Withdrawn.
4–139		ANSI/ADA Standard No. 48–2004 (R2015) Visible Light Curing Units	Withdrawn.
4–181	4–298	ISO 4049 Fifth edition 2019–05 Dentistry—Polymer-based restorative materials.	Withdrawn and replaced with newer version.
4–198	4–299	ISO 3107 Fifth edition 2022–09 Dentistry—Zinc oxide-eugenol cements and non-eugenol zinc oxide cements.	Withdrawn and replaced with newer version.
4–227	4–300	ISO 22674 Third edition 2022–08 Dentistry—Metallic materials for fixed and removable restorations and appliances.	Withdrawn and replaced with newer version.
4–231		ISO/TS 11405 Third edition 2015–02–01 Dentistry—Testing of adhesion to tooth structure.	Withdrawn.
4–240	4–301	ISO 21563 Second edition 2021–08 Dentistry—Hydrocolloid impression materials.	Withdrawn and replaced with newer version.
4–248	4–302	ISO 10477 Fourth edition 2020–10 Dentistry—Polymer-based crown and veneering materials.	Withdrawn and replaced with newer version.
4–249		ANSI/ADA Standard No. 19–2018 Elastometric Impression Materials	Withdrawn.
4–253		ANSI/ADA Standard No. 27–2016 Polymer-based Restorative Materials	Withdrawn. See 4–298.
4–264	4–303	ISO 9333 Third edition 2022–08 Dentistry—Brazing materials	Withdrawn and replaced with newer version.
4–267	4–304	ISO 21606 Second edition 2022–08 Dentistry—Elastomeric auxiliaries for use in orthodontics.	Withdrawn and replaced with newer version.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
		No new entries at this time.	
		F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
19–34		IEC 61010–1 Edition 3.1 2017–01 CONSOLIDATED VERSION Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements [Including: Corrigendum 1 (2019)].	Recognition restored.
		G. General Hospital/General Plastic Surgery (GH/GPS)	
6–253	6–486	ISO 10535 Third Edition 2021–10 Assistive products—Hoists for the transfer of persons—Requirements and test methods.	Withdrawn and replaced with newer version.
6–296	6–487	AAMI PB70:2022 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.	Withdrawn and replaced with newer version.
6–306	6–488	ASTM F1671/F1671M–22 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System.	Withdrawn and replaced with newer version.
6–321	6–489	IEC 60601–2–52 Edition 1.1 2015–03 CONSOLIDATED VERSION Medical electrical equipment—Part 2–52: Particular requirements for the basic safety and essential performance of medical beds.	Withdrawn and replaced with newer version.
6–357	6–490	ISO 10555–6 First edition 2015–04–15 Intravascular catheters—Sterile and single-use catheters—Part 6: Subcutaneous implanted ports [Including Amendment 1 (2019)].	Withdrawn and replaced with newer version.
6–402	6–491	ASTM F1670/F1670M–17a Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
6–425	6–492	ASTM F2100–23 Standard Specification for Performance of Materials Used in Medical Face Masks.	Withdrawn and replaced with newer version.
6–427	6–493	ASTM F2101–23 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*.	Withdrawn and replaced with newer version.
6–474	6–494	ASTM F3352/F3352M–23a Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–152	7–315	CLSI EP12 3rd Edition Evaluation of Qualitative, Binary Output Examination Performance.	Withdrawn and replaced with newer version.
7–244	7–316	CLSI NBS01 7th Edition Dried Blood Spot Specimen Collection for Newborn Screening.	Withdrawn and replaced with newer version.
7–308	7–317	CLSI M100, 33rd Edition Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
I. Materials			
8–200	8–597	ASTM F2003–02(2022) Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene After Gamma Irradiation in Air.	Withdrawn and replaced with newer version.
8–441	8–598	ASTM F3109–22 Standard Practice for Verification of Multi-Axis Force Measuring Platforms.	Withdrawn and replaced with newer version.
8–453	8–599	ASTM F1295–22 Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700).	Withdrawn and replaced with newer version.
8–467	8–600	ASTM F1978–22 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser.	Withdrawn and replaced with newer version.
8–506	8–601	ASTM F2516–22 Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials.	Withdrawn and replaced with newer version.
8–528	8–602	ASTM F2503–23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Withdrawn and replaced with newer version.
8–555	8–603	ASTM F1472–23 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400).	Withdrawn and replaced with newer version.
J. Nanotechnology			
18–15	18–23	ASTM E3025–22 Standard Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles.	Withdrawn and replaced with newer version.
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
9–67	9–145	ASTM D7661–18 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.	Withdrawn and replaced with newer version.
9–94	9–146	ISO 8600–4 Third Edition 2023–01 Endoscopes—Medical endoscopes and endotherapy devices—Part 4: Determination of maximum width of insertion portion.	Withdrawn and replaced with newer version.
9–125	9–147	ISO/CIE 11664–2 First edition 2022–08 Colorimetry—Part 2: CIE standard illuminants.	Withdrawn and replaced with newer version.
9–128	9–148	ISO/CIE 11664–6 Second edition 2022–08 Colorimetry—Part 6: CIEDE2000 Colour-difference formula.	Withdrawn and replaced with newer version.
9–143	.....	ISO 20696 First edition 2018–06 Corrected version 2019–12 Sterile urethral catheters for single use.	Extent of recognition.
M. Ophthalmic			
No new entries at this time.			
N. Orthopedic			
11–294	11–399	ASTM F1357–23 Standard Specification for Articulating Total Wrist Implants.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
O. Physical Medicine			
16–165	16–234	ISO 7176–14 Third Edition 2022 Wheelchairs—Part 14 Power and control systems for electrically powered wheelchairs and scooters—Requirements and test methods.	Withdrawn and replaced with newer version.
16–194	16–235	ISO 7176–25 Second Edition 2022 Wheelchairs—Part 25: Lead-acid batteries and chargers for powered wheelchairs—Requirements and test methods.	Withdrawn and replaced with newer version.
16–201	16–236	ISO 7176–19 Third Edition 2022 Wheelchairs—Part 19: Wheeled mobility devices for use as seats in motor vehicles.	Withdrawn and replaced with newer version.
P. Radiology			
12–6	12–350	IEC 60806 Edition 2.0 2022–11 Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis.	Withdrawn and replaced with newer version.
12–347	.....	IEC 60601–2–33 Edition 4.0 2022–08 Medical electrical equipment—Part 2–33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.	Transition period extended.
12–329	12–351	IEC 60601–2–43 Edition 3.0 2022–12 Medical electrical equipment—Part 2–43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
No new entries at this time.			
R. Sterility			
14–169	14–584	ASTM F2391–22 Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas.	Withdrawn and replaced with newer version.
14–456	14–585	ISO/TS 16775 Second edition 2021–11 Packaging for terminally sterilized medical devices—Guidance on the application of ISO 11607–1 and ISO 11607–2.	Withdrawn and replaced with newer version.
14–575	.....	ASTM F1980–21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	Transition period extended.
S. Tissue Engineering			
No new entries at this time.			

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 060. These entries are of standards not previously recognized by FDA.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. Anesthesiology		
No new entries at this time.		
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
3–185	Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging.	ANSI/AAMI PC76:2021.
3–186	Implants for surgery—Active implantable medical devices—Part 2: Cardiac pacemakers.	ISO 14708–2 Third edition 2019–09.
3–187	Implants for surgery—Active implantable medical devices—Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators).	ISO 14708–6 Second edition 2019–09.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
3–188	Non-invasive sphygmomanometers—Part 3: Clinical investigation of continuous automated measurement type.	ISO 81060–3 First edition 2022–12.
	D. Dental/ENT	
4–305	Dentistry—Central suction source equipment	ISO 10637 Second edition 2018–05.
4–306	Dentistry—Compressed air source equipment	ISO 22052 First edition 2020–06.
4–307	Dentistry—General requirements for instruments and related accessories used in dental implant placement and treatment.	ISO 13504 First edition 2012–07.
4–308	Implants for surgery—Active implantable medical devices—Part 7: Particular requirements for cochlear and auditory brainstem implant systems.	ISO 14708–7 Second edition 2019–12 (Corrected version 2020–05).
	E. General I (QS/RM)	
	No new entries at this time.	
	F. General II (ES/EMC)	
19–49	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.	IEC 60601–1 Edition 3.2 2020–08 CONSOLIDATED VERSION.
	G. GH/GPS	
6–495	Catheter systems for neuraxial application—Sterile and single-use catheters and accessories.	ISO 20698 First Edition 2018–07.
6–496	Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact.	ASTM F739–20.
	H. IVD	
	No new entries at this time.	
	I. Materials	
8–604	Standard Specification for Wrought Seamless or Welded and Drawn 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673).	ASTM F2257–22.
	J. Nanotechnology	
	No new entries at this time.	
	K. Neurology	
	No new entries at this time.	
	L. OB-Gyn/G/Urology	
9–149	Medical electrical equipment—Part 2–39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment.	IEC 60601–2–39 Edition 3.0 2018–04.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
	M. Ophthalmic	
	No new entries at this time.	
	N. Orthopedic	
	No new entries at this time.	
	O. Physical Medicine	
	No new entries at this time.	
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
	No new entries at this time.	
	R. Sterility	
14–586	Sterilization of health care products—Low temperature vaporized hydrogen peroxide—Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO 22441 First edition 2022–08.
14–587	Guidance on transferring health care products between radiation sterilization sources	AAMI TIR104:2022.
14–588	Compatibility of materials subjected to sterilization	AAMI TIR17:2017/(R)2020.
	S. Tissue Engineering	
	No new entries at this time.	

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *CDRHStandardsStaff@fda.hhs.gov.* To be considered, such recommendations should contain, at a minimum, the information available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16770 Filed 8–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3032]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3-CMC); Dipentylone; 2-Fluorodeschloroketamine (2-FDCK); Nitrous Oxide (N_2O); Carisoprodol; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is inviting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of eight drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. This notice requesting comments is required by the Controlled Substances Act (CSA).

DATES: Either electronic or written comments must be submitted by August 24, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 24, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3032 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3-CMC); Dipentylone; 2-Fluorodeschloroketamine (2-FDCK); Nitrous oxide (N_2O); Carisoprodol; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Edward (Greg) Hawkins, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5110, Silver Spring, MD 20993–0002, 301–796–0727, *edward.hawkins@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations (U.N. Secretary-General) and provide the U.N. Secretary-General with information in support of its opinion.

Paragraph (d)(2)(A) of the CSA (21 U.S.C. 811) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

II. WHO Notification

The Secretary of HHS received the following notice from WHO (nonrelevant text removed):

Ref.: C.L.22.2023

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of announcing that the 46th Expert Committee on Drug Dependence (ECDD) will meet from 16 to 20 October 2023, in Geneva, Switzerland. Given that WHO Expert Committee meetings are of a closed nature, this letter serves to notify Member States of the substances under review at the 46th ECDD, which are in the Annex I file, attached for reference.

WHO is mandated by the 1961 and 1971 International Drug Control Conventions to make recommendations to the UN Secretary-General on the need for and level of international control of psychoactive substances based on the advice of its independent scientific advisory body, the ECDD. To assess whether or not a psychoactive substance should be placed under international control, the ECDD convenes annually to review the potential of this substance to cause dependence, abuse and harm to health, as well as any therapeutic applications. In order to perform this review and make evidence-based decisions, the ECDD conducts medical, scientific, and public health evaluations of the selected psychoactive substances using the best available information.

Although the meetings are of a closed nature, Member States are invited to contribute to the ECDD review process by joining the 46th ECDD Information Session on 16 October 2023. The Information Session will be held virtually and allow interested parties to learn about present and future activities of the ECDD Secretariat, and to present information concerning substances under review to the 46th Expert Committee

for consideration in its deliberations. Registration information will be made available on the ECDD website in due course: *https://www.who.int/news-room/events/detail/2023/10/16/default-calendar/forty-sixth-expert-committee-on-drug-dependence.*

As in the past and in line with the publication ''*Guidance on the WHO review of psychoactive substances for international control*'' (EB126/2010/REC1, Annex 6),[1] Member States can also contribute to the ECDD review process by providing up to date and accurate information concerning the substances under review in advance of the meeting. For this purpose, and as per previous practice, a questionnaire will be sent to Member States to gather country information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 27 June 2023

[1] *https://apps.who.int/gb/ebwha/pdf_files/EB126-REC1/B126_REC1-en.pdf#page=90.*

Annex I

46th Expert Committee on Drug Dependence (ECDD) Substances for Review 16–20 October 2023

Critical reviews: The substances listed below have been proposed by WHO for critical review and are not currently under international control. Information was brought to WHO's attention that these substances are clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any Party. The Expert Committee will consider whether information presented during a critical review may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions.

Benzodiazepines
1. Bromazolam
2. Flubromazepam

Novel Synthetic Opioids
3. Butonitazene

Cathinones/stimulants
4. 3-Chloromethcathinone (3-CMC)
5. Dipentylone

Dissociative-type substances
6. 2-fluorodeschloroketamine (2-FDCK)

Pre-reviews: The substances listed below have been proposed for a pre-review. The purpose of a pre-review is to determine whether current information justifies an Expert Committee critical review. A pre-review is a preliminary analysis and findings at this stage should not determine whether the control status of a substance should be changed.

Medicines
7. Nitrous oxide
8. Carisoprodol

FDA has verified the website addresses contained in the WHO notice as of the date this document publishes in the **Federal Register**; however, websites are subject to change over time. Access to view the WHO questionnaire can be found at *https://www.who.int/groups/who-expert-committee-on-drug-dependence/46th-ecdd-documents.*

III. Substances Under WHO Review

Bromazolam is a triazolobenzodiazepine that produces agonist effects on gamma-aminobutyric acid (GABA) type-A channels through the benzodiazepine site. Through this mechanism of action, bromazolam can produce sedative and anxiolytic effects similar to other drugs of the benzodiazepine class. According to the National Forensic Laboratory Information System (NFLIS) database, there were 2,881 drug seizures of bromazolam in the United States from 2016 to May of 2023; however, some case reports are still pending for 2022 and 2023, so this number is increasing. Toxicology data indicate that bromazolam is typically detected in samples that include other drugs such as stimulants and opioids. This polydrug combination has led to the determination that bromazolam has played at least a contributory role in 152 confirmed deaths associated with the use of bromazolam. There are no commercial or approved medical uses for bromazolam in the United States, and it is not controlled under the CSA.

Flubromazepam is a compound of the benzodiazepine class that produces agonist effects on $GABA_A$ channels and can produce sedative and anxiolytic effects similar to other drugs of the class. Law enforcement data indicate that flubromazepam has been detected in 169 biological samples from 2019 through 2022. In 2022, 87 percent of those samples also contained fentanyl. There are no commercial or approved medical uses for flubromazepam in the United States and it is not controlled under the CSA.

Butonitazene is a novel synthetic mu-opioid receptor agonist of the benzimidazole structural class. Law enforcement data indicates that butonitazene appeared on the U.S. illicit markets as evidenced by their identification in forensic drug seizures and biological samples. The abuse liability of benzimidazole opioids is similar to other synthetic opioids. Butonitazene has been identified in toxicological samples from post-mortem cases. The public health risks attendant to the abuse of mu-opioid receptor agonists are well established and can result in drowsiness, nausea, vomiting, and respiratory depression leading to death. Butonitazene has no approved medical uses in the United States and is a schedule I substance under the CSA.

3-Chloromethcathinone (3-CMC) and dipentylone are synthetic stimulant designer drugs structurally similar to schedule I synthetic cathinones and schedule II stimulants like methamphetamine. Like other schedule I synthetic cathinones, 3-MMC and dipentylone are abused for their psychoactive effects. Adverse effects associated with the abuse of synthetic cathinones include agitation, hypertension, tachycardia, and death. According to NFLIS, dipentylone was first detected in the United States in 2014, and in 2022 there were 4,901 law enforcement seizures of the drug. Both 3-CMC and dipentylone have been detected in biological samples from toxicological drug tests and from postmortem samples. 3-CMC and dipentylone have no approved medical uses in the United States and both are schedule I substances under the CSA.

2-Fluorodeschloroketamine (2-FDCK) is a dissociative anesthetic related to ketamine. 2-FDCK is a novel psychoactive substance (NPS) that is used as a research chemical and is sometimes marketed as a legal high. In animals, 2-FDCK demonstrated a similar potential for abuse as ketamine in studies that compare measurements of reinforcing effects (*e.g.,* self-administration) and discriminative stimulus effects (*e.g.,* drug discrimination and conditioned place preference). As a result, 2-FDCK is presumed to produce psychoactive effects similar to ketamine such as sensory dissociation, derealization, analgesia, hallucinations, mania, and amnesia. 2-FDCK has been detected in biological samples from toxicological drug tests and from postmortem samples. 2-FDCK has no approved medical uses in the United States and is not a controlled substance under the CSA, although it is controlled in many European countries.

Nitrous oxide (N_2O) is an inhalable gas that is also known by the common names, laughing gas, nitrous, whippets, NOS, or hippy-crack. It is part of the dissociative class of hallucinogens and is thought to function through modulation of GABA and *N*-methyl-*D*-aspartate (NMDA) receptors. N_2O was first used in the late 1700s as an analgesic for dental and surgical operations. It is approved by FDA as a medical gas but has seen increasing use around the world for its subjective effects. These effects include, but are not limited to, dizziness, loss of motor control, euphoria, perceptual changes, numbness, amnesia, derealization, and altered acuity. N_2O is not controlled under the CSA.

Carisoprodol is a sedative-hypnotic that is used as a centrally acting muscle relaxant and hypnotic. Carisoprodol is a prodrug that is metabolized in the liver to form meprobamate which functions similarly to benzodiazepines and barbiturates. It is approved for medical use in the United States as a muscle relaxant and is typically prescribed in combination with analgesics to treat muscle pain. Scientific studies indicate that carisoprodol has a demonstrated abuse potential similar to benzodiazepines, and it is controlled under schedule IV under the CSA.

IV. Opportunity To Submit Domestic Information

As required by paragraph (d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the eight drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in late 2023. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by paragraph (d)(2)(B) of the CSA (21 U.S.C. 811).

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16812 Filed 8–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–0038]

Determination That CUBICIN (Daptomycin) Powder for Injection, 250 Milligrams/Vial and 500 Milligrams/Vial, and CUBICIN RF (Daptomycin) Powder for Injection, 500 Milligrams/Vial, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CUBICIN (daptomycin) Powder for Injection, 250 milligrams (mg)/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for daptomycin powder for injection, 250 mg/vial and 500 mg/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Tereza Hess, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993–0002, 202–768–5659, *tereza.hess@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, initially approved on September 12, 2003, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, initially approved on July 6, 2016, are the subjects of NDA 021572, held by Cubist Pharmaceuticals, LLC. CUBICIN and CUBICIN RF are indicated for treatment of complicated skin and skin structure infections in adult and pediatric patients (1 to 17 years of age), and *Staphylococcus aureus* bloodstream infections (bacteremia) in adult patients including those with right-sided infective endocarditis. CUBICIN is also indicated for treatment of *S. aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).

CUBICIN (daptomycin) Powder for Injection, 250 mg/vial is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated June 22, 2021, Cubist Pharmaceuticals, LLC notified FDA that CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated March 30, 2022, Cubist Pharmaceuticals, LLC notified FDA that CUBICIN (daptomycin) Powder for Injection, 500 mg/vial was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated January 3, 2023 (Docket No. FDA–2023–P–0038), under 21 CFR 10.30, requesting that the Agency determine whether CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial

strengths, these strengths have also been discontinued. On our own initiative, we have also determined whether these strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16775 Filed 8–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1530]

Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs).'' This guidance provides applicants and manufacturers of drugs, including prescription and over-the-counter (OTC) drug products, with a recommended framework for predicting the mutagenic and carcinogenic potential of NDSRIs that could be present in drug products and recommends acceptable intake (AI) limits for NDSRIs. NDSRIs, which are a subcategory of nitrosamine impurities that share structural similarity to the active pharmaceutical ingredient (API) in drug products, typically lack compound-specific mutagenicity and carcinogenicity data to inform safety assessments. This guidance provides a recommended methodology for AI determination that uses structural features of NDSRIs to generate a predicted carcinogenic potency categorization and corresponding recommended AI limit that manufacturers and applicants can apply, in the absence of other FDA-recommended AI limits, in their evaluation of potential impurities in their drug products.

DATES: The announcement of the guidance is published in the **Federal Register** on August 7, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1530 for ''Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and

contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jason Bunting, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 301–796–1292.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs).'' FDA is implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). FDA made this determination because of the importance of providing additional timely information to manufacturers and applicants regarding recommended AI limits of NDSRIs, a class of nitrosamine impurities that has been identified in many drug products and also could be present in APIs. This guidance applies to drugs, including prescription and OTC drug products that are the subject of an approved or pending new drug application (NDA) or abbreviated new drug application (ANDA), as well as products [1] not marketed under a drug application, including nonprescription drugs subject to section 505G (21 U.S.C. 355h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (*i.e.,* OTC monograph drugs) or are otherwise subject to current good manufacturing practice. This guidance also applies to prescription and OTC drug products in clinical development. In addition, this guidance applies to certain biological products that contain chemically synthesized fragments or biologic-led combination products that contain a drug constituent part whether such products are in development or the subject of an approved or pending biologics license application (BLA). The recommendations in this guidance apply to both drug product and drug substance manufacturers.

This guidance provides manufacturers and applicants of drugs with a recommended framework for predicting the mutagenic and carcinogenic potential of NDSRIs that could be present in drug products and recommends AI limits for NDSRIs. This approach will assist manufacturers and applicants in taking steps to detect and prevent unacceptable levels of nitrosamine impurities in drug products. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation (§ 10.115(g)(3)(D)).

Nitrosamine compounds have the potential to be potent genotoxic agents in several animal species, and some are classified as probable or possible human carcinogens. Nitrosamines are included in a group of high potency mutagenic carcinogens referred to as ''cohort of concern'' compounds in the International Council for Harmonisation (ICH) guidance for industry entitled ''M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk'' (March 2018). In 2020, FDA published a guidance for industry, ''Control of Nitrosamine Impurities in Human Drugs,'' (85 FR 55017, September 3, 2020) (Nitrosamine Guidance), recommending that manufacturers of APIs and drug products take steps to detect and prevent unacceptable levels of nitrosamine impurities in drug products, or avoid their presence when feasible, and updated the guidance on February 24, 2021.

NDSRIs are a class of nitrosamines sharing structural similarity to the API, and thus, differ in certain respects from small molecule nitrosamine impurities specified in the Nitrosamine Guidance. NDSRIs are unique to each API and are generally formed in a drug product through nitrosation of APIs (or API fragments) that have secondary or tertiary amines when exposed to nitrosating agents such as residual nitrites in excipients used to formulate the drug product. NDSRIs that have been recently identified in a number of drug products generally lack carcinogenicity and mutagenicity data (typically from animal studies) from which an AI can be determined. Based on the chemical structure of certain drugs, there is a risk of NDSRIs forming in a substantial number of drug products; however, it is currently unknown if all or some NDSRIs are in fact high-potency mutagenic carcinogens. It is challenging to establish an AI limit for NDSRIs because of the lack of available mutagenicity data and robust carcinogenicity data from which applicants would otherwise determine AI limits. These challenges have led to some applicants and manufacturers conducting unnecessary studies or, in some cases, discontinuing drug products from the market.

FDA is recommending a predicted carcinogenic potency categorization method that assigns a recommended AI limit to an NDSRI based on the NDSRI's activating and deactivating structural features. Predicted carcinogenic potency categories enable manufacturers to determine recommended AI limits for NDSRIs in APIs and drug products and to facilitate development of methods for confirmatory testing. Potency categorization offers a scientifically based predictive solution to recommending AI limits for data-poor NDSRIs, for which suitable surrogates with robust carcinogenicity data are not available.

The recommendations in this guidance provide a risk-based safety assessment of NDSRIs and can be used by applicants and manufacturers to identify AI limits for NDSRIs in their drug products and APIs in conjunction with the recommendations in the Nitrosamine Guidance. If FDA communicates another FDA-recommended AI limit for a specific NDSRI, manufacturers and applicants should apply that recommended AI

[1] For the purposes of this guidance, we use the term ''drug'' or ''drug product'' to refer to human drug and biological products, including drug-led and biologic-led combination products, regulated by the Center for Drug Evaluation and Research, unless otherwise specified.

limit rather than the AI limit recommended in this guidance based on predicted carcinogenic potency. In general, FDA would expect manufacturers and applicants to control impurities within the recommended AI limit. Additionally, manufacturers and applicants should continue to pursue mitigation efforts to reduce or remove NDSRIs in their drug products.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 pertaining to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to NDAs and ANDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to BLAs have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 201 pertaining to OTC monograph drug products have been approved under OMB control number 0910–0340.

III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16814 Filed 8–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Confederated Tribes of Grand Ronde in the State of Oregon

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Confederated Tribes of Grand Ronde (CTGR) in the State of Oregon to include the county of Clackamas in the State of Oregon. The current PRCDA for the CTGR includes the Oregon counties of Washington, Polk, Yamhill, Marion, Multnomah, and Tillamook. The CTGR members residing outside of the PRCDA are eligible for direct care services, however, they are not eligible for Purchased/Referred Care (PRC) services. The sole purpose of this expansion would be to authorize additional CTGR members and beneficiaries to receive PRC services.

DATES: Comments must be submitted September 6, 2023.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a Comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Carl Mitchell, Director, Division of Regulatory and Policy Coordination, Indian Health Service, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, Maryland 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the above address.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above.

If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443–1116 in advance to schedule your arrival with a staff member.

FOR FURTHER INFORMATION CONTACT: CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop: 10E85C, Rockville, Maryland 20857. Telephone (301) 443–0969 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

Background: The IHS provides services under regulations in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC, but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation, 42 CFR 136.22(a)(6). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may from time to time, redesignate areas within the United States for inclusion in or exclusion from a PRCDA, 42 CFR 136.22(b). The regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of PRC.

Additionally, the regulations require that any redesignation of a PRCDA must be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553), 42 CFR 136.22 (c). In compliance with this requirement, the IHS is publishing this Notice and requesting public comments.

The CTGR is located in Grand Ronde, Oregon, which is located in Western Oregon where it has an 11,500-acre reservation in Yamhill County. The Tribe has requested to add Clackamas County to their PRCDA which is currently comprised of Washington, Polk, Yamhill, Marion, Multnomah, and Tillamook Counties in Oregon. Multnomah and Marion Counties are contiguous to the requested expansion into Clackamas County, and part of ceded lands from the Willamette Valley Treaty.

The CTGR's PRC Program is operated under a long standing Title V agreement. The Portland Area IHS estimates there are currently 179 Tribal members who live within Clackamas County and would become PRC eligible through this proposed expansion. The Tribe states that many of these members routinely travel to Portland, or to the Tribal facilities in Grand Ronde, to seek care as they are not currently eligible for PRC. They are also active members of the community and routinely participate in Tribal elections, General Council meetings, and Tribal events. The Tribe would like to recognize them as eligible for PRC. Accordingly, the IHS proposes to expand the PRCDA of the CTGR to include the Oregon county of Clackamas.

Under 42 CFR 136.23, those otherwise eligible Indians who do not reside on a reservation, but reside within a PRCDA, must be either members of the Tribe or other IHS beneficiaries who maintain close economic and social ties with the Tribe. In this case, applying the aforementioned PRCDA redesignation criteria required by operative regulations codified at 42 CFR part 136, subpart C, the following findings are made:

1. By expanding the PRCDA to include Clackamas County, the CTGR's eligible population will be increased by an estimated 179 Tribal members residing in Clackamas County.

2. The IHS finds that the Tribal members within the expanded PRCDA are socially and economically affiliated with CTGR based on a letter from the CTGR, dated May 19, 2021, which noted that the CTGR members residing in Clackamas County are active members of the community and routinely participate in Tribal elections, General Council meetings, and Tribal events.

3. Clackamas County in the State of Oregon is ''on or near'' the reservation, as it maintains a common boundary with the current PRCDA consisting of the counties of Washington, Polk, Yamhill, Marion, Multnomah, and Tillamook in the State of Oregon.

4. The CTGR administers the PRC program and will use its existing Federal allocation for PRC, along with Tribal resources, to provide services to the expanded population. The Tribe acknowledged that no additional financial resources will be allocated by the IHS to the Portland Area IHS to provide services to CTGR members residing in Clackamas County in the State of Oregon.

This Notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

Roselyn Tso,

Director, Indian Health Service.

[FR Doc. 2023–16843 Filed 8–4–23; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Information Collection: Indian Self-Determination and Education Assistance Act Contracts

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments; request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, ''Indian Self-Determination and Education Assistance Act Contracts,'' Office of Management and Budget (OMB) Control Number 0917–0037. The IHS is requesting OMB to approve an extension for this collection, which expires on August 31, 2023.

DATES:

Comment Due Date: September 6, 2023. Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

ADDRESSES:

Direct Your Comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer at: *Evonne.Bennett@ihs.gov* or 240–472–1996.

SUPPLEMENTARY INFORMATION: This notice announces our intent to seek an extension of the collection already approved by OMB, and to solicit comments on specific aspects of the information collection. There were two public comments received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted to OMB. A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID IHS–2023–0001).

Comments: Both comments did not pertain to the collection, or the IHS.

Response to Comment: The Agency does not have a response to the comments.

Information Collection Title: Indian Self-Determination and Education Assistance Act Contracts, 25 CFR part 900, 0917–0037.

Type of Information Collection Request: Extension of currently approved collection.

Form Numbers: 0917–0037.

Need and Use of Information Collection: In 1975, Congress enacted the Indian Self-Determination and Education Assistance Act (ISDEAA) to authorize Tribes and Tribal organizations (T/TO) to assume control of certain Federal programs, *e.g.,* health care programs that certain Federal agencies would otherwise provide to American Indians and Alaska Natives.

The T/TO that intend to establish a new or expanded Title I self-determination contract with the IHS are required to provide proposal information identified at 25 CFR 900.8, which describes what a contract proposal must contain. This information is used by the IHS to determine applicant eligibility, evaluate applicant capabilities, protect the service

population, and safeguard Federal funds and resources.

Subpart C contains provisions relating to the initial contract proposal contents (*i.e.,* 25 CFR 900.8). The proposal contents consist of required items that must be included in a proposal for a new or expanded program. These items include basic information about the T/TO and program to be contracted, such as: name and address; authorizing resolution; date of submission of proposal; description of geographical service area; estimated number of people to be served; brief statement of program functions, services or activities to be performed; description of the proposed program; financial, procurement, and property management standards; description of reports to be provided; staff qualifications, if any; budget information; and waiver information; as requested. The information is collected at the time the T/TO makes an initial application to contract a program.

Subpart F contains the minimum standards for the management systems used by the T/TO when carrying out a self-determination contract. Sections 900.40–44, 48–49, 53, 55, and 60 discuss the information and record keeping requirements of the T/TO regarding the financial, procurement, and property management standards.

Subpart G provides for the negotiation of all reporting and data requirements between the T/TO and the Secretary (*e.g.,* 25 CFR 900.65). The information collected is directly related to the operation of the program and is negotiated on a contract by contract basis. The IHS uses the information to monitor contract operations and determine if satisfactory services are being provided. The information is collected and reported during the operation of the contract based on the terms negotiated in each contract.

Subpart I establishes procedures regarding the donation of excess and surplus Federal property to T/TO, and the acquisition of property with funds provided under a self-determination contract. This subpart addresses the procedures to be followed when the T/TO wish to acquire excess IHS property, and excess or surplus government property from other agencies (*e.g.,* 25 CFR 900.97). This subpart also addresses the process for a T/TO to request that real property be placed ''in trust.'' The IHS uses the information to determine what property the T/TO want to acquire and how the property will be used. The information is collected and reported when the T/TO submit a request for excess and surplus Federal property.

Subpart J addresses the process by which the T/TO may contract for construction activities and sets forth minimum requirements for contract proposals (*e.g.,* 25 CFR 900.110–133). Among other things, the subpart requires the T/TO to submit descriptions of standards when proposing to contract a construction project. These standards include use of licensed and qualified architects and engineers; applicable health and safety standards; adherence to applicable Federal, State, or Tribal building codes and engineering standards; structural integrity; accountability for funds; adequate competition for sub-contracting under Tribal or other applicable law; the commencement, performance, and completion of the contract; adherence to project plans and specifications (including any applicable Federal construction guidelines and manuals); the use of proper materials and workmanship; necessary inspection and testing; and a process for changes, modifications, stop work and termination of the work when warranted. In addition to the above, additional information is required when T/TO are proposing to contract design and construction activity.

Subpart L (25 CFR 900.150 *et seq.*) provides the appeal procedures available to the T/TO. Section 900.158 explains how to file a notice of appeal with the Interior Board of Indian Appeals (IBIA) and what the notice should contain. The IBIA receives the notice of appeal from the T/TO; and the IHS receives a copy of information sent to the IBIA; and section 900.166 provides instructions for submitting a written statement of objections concerning an Administrative Law Judge's decision. The information is collected and reported when the T/TO request an appeal conference, file a notice of appeal, or request an appeal time extension, or submit objections for an Administrative Law Judge's decision (*i.e.,* 900.166).

Subpart N covers the process for post-award contract disputes (*e.g.,* 25 CFR 900.215–230). Section 900.219 explains how the T/TO submit a Contract Disputes Act (CDA) claim. The IHS needs and uses the information to evaluate and approve or disapprove a CDA claim. The information is collected and reported as needed when such a claim is filed. The CDA, 41 U.S.C. 7101 *et seq.,* sets forth the information required to be submitted for a claim. The regulations, including at 900.220, only restate those statutory requirements and do not require any additional information.

Affected Public: Federally recognized Indian Tribes and Tribal organizations.

Type of Respondents: Governments and individuals.

Estimated Number of Responses: 243.

Estimated Time per Response: An average of 30 hours per response.

Frequency of Response: Each time programs, functions, services, or activities are contracted from the IHS under the ISDEAA, currently 243 per year.

Estimated Total Annual Hour Burden: 7,290.

There are no capital costs, operating costs and/or maintenance costs to respondents.

Requests for Comments: Your written comments and/or suggestions are invited on one or more of the following points:

(a) Whether the information collection activity is necessary to carry out an agency function;

(b) Whether the agency processes the information collected in a useful and timely fashion;

(c) The accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information);

(d) Whether the methodology and assumptions used to determine the estimates are logical;

(e) Ways to enhance the quality, utility, and clarity of the information being collected; and

(f) Ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Roselyn Tso,

Director, Indian Health Service.

[FR Doc. 2023–16706 Filed 8–4–23; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting.

The meeting will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance

with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Board of Scientific Counselors.

Date: October 26, 2023.

Open: 11:00 a.m. to 12:35 p.m.

Agenda: Program Discussion and Investigator Report.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Closed: 12:35 p.m. to 2:30 p.m.

Agenda: To review and evaluate personal qualifications, performance, and competence of individual investigators.

Contact Person: Valerie Florance, Ph.D., Acting Scientific Director, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 240–603–9822, *florancev@mail.nih.gov.*

Any member of the public may submit written comments no later than 15 days in advance of the meeting. Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Open sessions of this meeting will be broadcast to the public, and available for viewing at *https://videocast.nih.gov* on October 26, 2023. Please direct any questions to the Contact Person listed on this notice.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: August 2, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16766 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Devices Panel.

Date: August 7, 2023.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Rockville, MD 20852, 301–435–6033, *rajarams@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: August 2, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16754 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Team-Based Design in BME Education and ESTEEMED Programs (R25) Review.

Date: September 22, 2023.

Time: 10:15 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Dem II, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Yoon-Young Jang, MD, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 959, Bethesda, MD 20892, (301) 451–3397, *yoon-young.jang@nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Technology for Health Disparities RFA review SEP.

Date: November 3, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Dem II, Suite 920, 6707 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Yoon-Young Jang, MD, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 959, Bethesda, MD 20892, (301) 451–3397, *yoon-young.jang@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.)

Dated: August 1, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16715 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bioengineering of Neuroscience and Vision Technologies.

Date: August 14, 2023.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tina Tze-Tsang Tang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Suite 3030, Bethesda, MD 20817, (301) 435–4436, *tangt@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 1, 2023.

Tyeshia Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16767 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting. In person attendees should register at (*https://www.nibib.nih.gov/about-nibib/advisory-council/registration*) in advance of the meeting so that the meeting organizers can plan accordingly.

The meeting will be videocast and can be accessed from the NIH Videocasting website at (*https://videocast.nih.gov/watch=51083*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering, NACBIB, September 2023.

Date: September 14, 2023.

Open: 09:00 a.m. to 12:20 p.m.

Agenda: Report from the Institute Director, Council Members and other Institute Staff.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Room 1135/45/55, Rockville, MD 20852.

Closed: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Room 1135/45/55, Rockville, MD 20852.

Contact Person: Kathy Salaita, Ph.D., Acting Associate Director for Research Administration, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Bethesda, MD 20892, *kathy.salaita@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nibib.nih.gov/about-nibib/advisory-council* where an agenda and any additional information for the meeting will be posted when available.

Dated: August 1, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16716 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; BRAIN Initiative: New Concepts and Early-Stage Research for Recording and Modulation in the Nervous System (R21).

Date: September 7, 2023.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Designated Federal Official, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700 B Rockledge, Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 31, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16714 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special

Emphasis Panel; Small Business Cooperative Agreements Review.

Date: November 2, 2023.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1062, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ming Yan, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1062, Bethesda, MD 20892, (301) 451–2853, *ming.yan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 1, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16705 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID 2023 DMID Omnibus BAA (HHS–NIH–NIAID–BAA2023–1), Research Area 001—Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases (N01).

Date: September 1, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 903 South 4th Street, Hamilton, MT 59840 (Virtual Meeting).

Contact Person: Dylan P. Flather, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 903 South 4th Street, Hamilton, MT 59840, (406) 802–6209, *dylan.flather@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 1, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16768 Filed 8–4–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0582]

National Navigation Safety Advisory Committee; Vacancies

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard seeks applications to fill two member vacancies on the National Navigation Safety Advisory Committee (Committee). This Committee advises the Secretary of Homeland Security and the Coast Guard on matters relating to maritime collisions, allisions, and groundings; Inland Rules of the Road; International Rules of the Road; navigation regulations and equipment, routing measures, marine information, and aids to navigation systems.

DATES: Completed applications should reach the U.S. Coast Guard on or before October 6, 2023.

ADDRESSES: Applications must include: (a) a cover letter expressing interest in an appointment to the National Navigation Safety Advisory Committee, (b) a resume detailing the applicant's relevant experience for the position applied for, and (c) a brief biography. Applications should be submitted via email with subject line ''NNAVSAC Committee Application'' to *George.H.Detweiler@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. George Detweiler, Alternate Designated Federal Officer of the National Navigation Safety Advisory Committee; telephone 202–372–1566 or email at *George.H.Detweiler@uscg.mil.*

SUPPLEMENTARY INFORMATION: The National Navigation Safety Advisory Committee is a Federal advisory committee. The Committee must operate under the provisions of the *Federal Advisory Committee Act,* (Pub. L. 117–286, 5 U.S.C. ch. 10), and 46 U.S.C. 15109.

The Committee was established on December 4, 2018, by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018* (Pub. L. 115–282, 132 Stat 4192), and is codified in 46 U.S.C. 15107. In accordance with 46 U.S.C. 15109(a), the Committee is required to hold meetings at least once a year. We expect the Committee to meet at least twice a year, but it may meet even more. The meetings may be held virtually or held at locations across the country selected by the U.S. Coast Guard.

Under provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31st of the third full year after the effective date of your appointment. The Secretary of Homeland Security may require an individual to have passed an appropriate security background examination before appointment to the Committee, 46 U.S.C. 15109(f)(4).

All members serve at their own expense and receive no salary or other compensation from the Federal Government. The only compensation the members may receive is for travel expenses, including per diem in lieu of subsistence, and/or actual and reasonable expenses incurred in the performance of their direct duties at the Committee in accordance with Federal Travel Regulations. If you are appointed as a member of the Committee, you will be required to sign a Non-Disclosure Agreement and a Gratuitous Services Agreement.

In this solicitation for a Committee Members, we will consider applications for two (2) positions to be selected from the following membership categories:

a. Commercial vessel owners or operators
b. Professional mariners
c. Recreational boaters
d. The recreational boating industry
e. State agencies responsible for vessel or port safety
f. The Maritime Law Association

Each member of the Committee must have expertise, knowledge, and experience in matters relating to the function of the Committee which is to advise the Secretary of Homeland Security on matters relating to maritime collisions, allisions, and groundings;

Inland Rules of the Road; International Rules of the Road; navigation regulations and equipment, routing measures, marine information, and aids to navigation systems.

The members who will fill the two positions described above will be appointed to represent the interest of their respective groups and viewpoints and are not Special Government Employees as defined in 18 U.S.C. 202(a).

In order for the Department, to fully leverage broad-ranging experience and education, the National Navigation Safety Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the Nation's people.

If you are interested in applying to become a member of the Committee, your application must be emailed to *George.H.Detweiler@uscg.mil* as provided in the **ADDRESSES** section of this notice. Applications must include: (a) a cover letter expressing interest in an appointment to the National Navigation Safety Advisory Committee, (b) a resume detailing the applicant's relevant experience for the position applied for, and (c) a brief biography of the applicant by the deadline in the **DATES** section of this notice.

The U.S. Coast Guard will not consider incomplete or late applications.

Dated: August 1, 2023.

Michael D. Emerson,

Director of Marine Transportation Systems.

[FR Doc. 2023–16749 Filed 8–4–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65. The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Colorado:					
Boulder (FEMA Docket No.: B–2335).	City of Boulder (22–08–0586P).	The Honorable Aaron Brockett, Mayor, City of Boulder, 1777 Broadway Street, Boulder, CO 80306.	City Hall, 1777 Broadway Street, Boulder, CO 80306.	Jul. 17, 2023	080024
Grand (FEMA Docket No.: B–2335).	Town of Fraser (22–08–0389P).	Ed Cannon, Manager, Town of Fraser, P.O. Box 370, Fraser, CO 80442.	Planning Department, 153 Fraser Avenue, Fraser, CO 80442.	Jun. 23, 2023	080073

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Grand (FEMA Docket No.: B–2335).	Unincorporated areas of Grand County (22–08–0389P).	Edward T. Moyer, Grand County Manager, P.O. Box 264, Hot Sulphur Springs, CO 80451.	Grand County Community Development Department, 308 Byers Avenue, Hot Sulphur Springs, CO 80451.	Jun. 23, 2023	080280
Florida:					
Monroe (FEMA Docket No.: B–2341).	Village of Islamorada (23–04–0726P).	The Honorable Joseph Buddy Pinder III, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	Jul. 10, 2023	120424
Osceola (FEMA Docket No.: B–2341).	City of St. Cloud (22–04–0527P).	The Honorable Nathan Blackwell, Mayor, City of St. Cloud, 1300 9th Street, St. Cloud, FL 34769.	City Hall, 1300 9th Street, St. Cloud, FL 34769.	Jul. 7, 2023	120191
Osceola (FEMA Docket No.: B–2341).	Unincorporated areas of Osceola County (22–04–0527P).	Donald Fisher, Osceola County Manager, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Public Works Department, 1 Courthouse Square, Suite 3100, Kissimmee, FL 34741.	Jul. 7, 2023	120189
Palm Beach (FEMA Docket No.: B–2341).	Village of Tequesta (22–04–0040P).	The Honorable Molly Young, Mayor, Village of Tequesta, 345 Tequesta Drive, Tequesta, FL 33469.	Building Department, 345 Tequesta Drive, Tequesta, FL 33469.	Jul. 10, 2023	120228
Volusia (FEMA Docket No.: B–2335).	City of Edgewater (22–04–4207P).	The Honorable Diezel DePew, Mayor, City of Edgewater, P.O. Box 100, Edgewater, FL 32132.	Stormwater Department, 409 Mango Tree Drive, Edgewater, FL 32132.	Jul. 14, 2023	120308
Volusia (FEMA Docket No.: B–2335).	Unincorporated areas of Volusia County (22–04–4207P).	George Recktenwald, Manager, Volusia County, 123 West Indiana Avenue, DeLand, FL 32720.	Volusia County Thomas C. Kelly Administration Center, 123 West Indiana Avenue, DeLand, FL 32720.	Jul. 14, 2023	125155
Michigan:					
Genesee (FEMA Docket No.: B–2341).	City of Flint (22–05–1981P).	The Honorable Sheldon Neeley, Mayor, City of Flint, 1101 South Saginaw Street, Flint, MI 48502.	Department of Public Works, 1101 South Saginaw Street, Flint, MI 48502.	Jul. 10, 2023	260076
Genesee (FEMA Docket No.: B–2341).	Township of Flint (22–05–1981P).	Karyn Miller, Township of Flint Supervisor, 1490 South Dye Road, Flint, MI 48532.	Building Department, 1490 South Dye Road, Flint, MI 48532.	Jul. 10, 2023	260395
Genesee (FEMA Docket No.: B–2341).	Township of Genesee (22–05–1981P).	Daniel Eashoo, Township of Genesee Supervisor, 7244 North Genesee Road, Genesee, MI 48437.	Department of Public Works, 7244 North Genesee Road, Genesee, MI 48437.	Jul. 10, 2023	260078
New Mexico:					
Curry (FEMA Docket No.: B–2335).	City of Clovis (22–06–0491P).	The Honorable Mike Morris, Mayor, City of Clovis, 321 North Connelly Street, Clovis, NM 88101.	City Hall, 321 North Connelly Street, Clovis, NM 88101.	Jul. 13, 2023	350010
Curry (FEMA Docket No.: B–2335).	Unincorporated areas of Curry County (22–06–0491P).	Lance A. Pyle, Curry County Manager, 417 Gidding Street, Suite 100, Clovis, NM 88101.	Curry County Clerk's Office, 417 Gidding Street, Suite 130, Clovis, NM 88101.	Jul. 13, 2023	350127
North Carolina: Orange (FEMA Docket No.: B–2334).	Town of Chapel Hill (22–04–2985P).	The Honorable Pam Hemminger, Mayor, Town of Chapel Hill, 405 Martin Luther King Jr. Boulevard, Chapel Hill, NC 27514.	Town Hall, 405 Martin Luther King Jr. Boulevard, Chapel Hill, NC 27514.	Jul. 28, 2023	370180
South Carolina:					
Jasper (FEMA Docket No.: B–2341).	City of Hardeeville (22–04–1790P).	Michael J. Czymbor, Manager, City of Hardeeville, 205 Main Street, Hardeeville, SC 29927.	City Hall, 205 Main Street, Hardeeville, SC 29927.	Jun. 29, 2023	450113
Jasper (FEMA Docket No.: B–2341).	Unincorporated areas of Jasper County (22–04–1790P).	The Honorable Barbara Clark, Vice Chair, Jasper County Council, 358 3rd Avenue, Ridgeland, SC 29936.	Jasper County Planning and Building Services Department, 358 3rd Avenue, Ridgeland, SC 29936.	Jun. 29, 2023	450112
Texas:					
Bexar (FEMA Docket No.: B–2341).	City of Helotes (21–06–3308P).	The Honorable Rich Whitehead, Mayor, City of Helotes, P.O. Box 507, Helotes, TX 78023.	City Hall, 12951 Bandera Road, Helotes, TX 78023.	Jul. 10, 2023	481643
Collin (FEMA Docket No.: B–2335).	City of Lucas (22–06–1259P).	The Honorable Jim Olk, Mayor, City of Lucas, 665 Country Club Road, Lucas, TX 75002.	Public Works Department, 665 Country Club Road, Lucas, TX 75002.	Jun. 26, 2023	481545
Collin (FEMA Docket No.: B–2335).	City of Parker (22–06–1259P).	The Honorable Lee Pettle, Mayor, City of Parker, 5700 East Parker Road, Parker, TX 75002.	Public Works Department, 5700 East Parker Road, Parker, TX 75002.	Jun. 26, 2023	480139
Collin (FEMA Docket No.: B–2335).	Unincorporated areas of Collin County (22–06–1259P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Engineering Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	Jun. 26, 2023	480130
Dallas (FEMA Docket No.: B–2341).	City of Coppell (22–06–1246P).	The Honorable Wes Mays, Mayor, City of Coppell, P.O. Box 9478, Coppell, TX 75019.	Department of Public Works, 265 East Parkway Boulevard, Coppell, TX 75019.	Jul. 10, 2023	480170
Ellis (FEMA Docket No.: B–2334).	City of Grand Prairie (22–06–2161P).	Steve Dye, Manager, City of Grand Prairie, P.O. Box 534045, Grand Prairie, TX 75053.	City Hall, 300 West Main Street, Grand Prairie, TX 75050.	Jul. 3, 2023	485472
Ellis (FEMA Docket No.: B–2334).	City of Midlothian (22–06–2960P).	The Honorable Richard Reno, Mayor, City of Midlothian, 104 West Avenue E, Midlothian, TX 76065.	Engineering Department, 104 West Avenue E, Midlothian, TX 76065.	Jul. 14, 2023	480801
Fannin (FEMA Docket No.: B–2335).	Unincorporated areas of Fannin County (22–06–0044P).	The Honorable Randy Moore, Fannin County Judge, 101 East Sam Rayburn Drive, Suite 214, Bonham, TX 75418.	Fannin County Emergency Management Department, 2375 Silo Road, Bonham, TX 75418.	Jul. 5, 2023	480807
Harris (FEMA Docket No.: B–2341).	Unincorporated areas of Harris County (22–06–0855P).	The Honorable Lina Hidalgo, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Permits Office, 1111 Fannin Street, 8th Floor, Houston, TX 77002.	Jul. 3, 2023	480287

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Tarrant (FEMA Docket No.: B–2341).	City of Grapevine (22–06–1246P).	The Honorable William D. Tate, Mayor, City of Grapevine, P.O. Box 95104, Grapevine, TX 76099.	City Hall, 200 South Main Street, Grapevine, TX 76051.	Jul. 10, 2023	480598
Travis (FEMA Docket No.: B–2335).	City of Round Rock (22–06–0823P).	The Honorable Craig Morgan, Mayor, City of Round Rock, 221 East Main Street, Round Rock, TX 78664.	City Hall, 221 East Main Street, Round Rock, TX 78664.	Jul. 10, 2023	481048
Travis (FEMA Docket No.: B–2335).	Unincorporated areas of Travis County (22–06–0823P).	The Honorable Andy Brown, Travis County Judge, P.O. Box 1748, Austin, TX 78767.	Travis County Transportation and Natural Resources Department, 700 Lavaca Street, 5th Floor, Austin, TX 78701.	Jul. 10, 2023	481026
Williamson (FEMA Docket No.: B–2335).	Unincorporated areas of Williamson County (22–06–2448P).	The Honorable Bill Gravell, Jr., Williamson County Judge, Mayor, City of Keller, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County Engineering Department, 3151 Southeast Inner Loop, Georgetown, TX 78626.	Jul. 13, 2023	481079
Utah:					
Washington (FEMA Docket No.: B–2335).	City of St. George (22–08–0422P).	John Willis, Manager, City of St. George, 175 East 200 North, St. George, UT 84770.	Public Works and Engineering Department, 175 East 200 North, St. George, UT 84770.	Jun. 30, 2023	491177
Virginia:					
Loudoun (FEMA Docket No.: B–2335).	Unincorporated areas of Loudoun County (22–03–1016P).	Tim Hemstreet, Loudoun County Administrator, 1 Harrison Street, Southeast, 5th Floor, Leesburg, VA 20175.	Loudoun County Government Center, 1 Harrison Street Southeast, 3rd Floor, MSC #60, Leesburg, VA 20175.	Jul. 10, 2023	510090

[FR Doc. 2023–16742 Filed 8–4–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002; Internal Agency Docket No. FEMA–B–2316]

Proposed Flood Hazard Determinations for Collin County, Texas and Incorporated Areas

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its proposed notice concerning proposed flood hazard determinations, which may include the addition or modification of any Base Flood Elevation, base flood depth, Special Flood Hazard Area boundary or zone designation, or regulatory floodway (herein after referred to as proposed flood hazard determinations) on the Flood Insurance Rate Maps and, where applicable, in the supporting Flood Insurance Study reports for Collin County, Texas and Incorporated Areas.

DATES: This withdrawal is effective August 7, 2023.

ADDRESSES: You may submit comments, identified by Docket No. FEMA–B–2316, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: On March 1, 2023, FEMA published a proposed notice at 88 FR 12974, proposing flood hazard determinations for Collin County, Texas and Incorporated Areas. FEMA is withdrawing the proposed notice.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2023–16744 Filed 8–4–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002; Internal Agency Docket No. FEMA–B–2358]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised

flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Arizona:						
Pima	Town of Marana (23–09–0611P).	The Honorable Ed Honea, Mayor, Town of Marana, 11555 West Civic Center Drive, Marana, AZ 85653.	Engineering Department, Marana Municipal Complex, 11555 West Civic Center Drive, Marana, AZ 85653.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 23, 2023	040118
Yavapai	Unincorporated Areas of Yavapai County (22–09–1395P).	The Honorable James Gregory, Chair, Board of Supervisors, Yavapai County, 1015 Fair Street, 3rd Floor, Prescott, AZ 86305.	Yavapai County Flood Control District, 1120 Commerce Drive, Prescott, AZ 86305.	*https://msc.fema.gov/portal/advanceSearch.*	Sep. 14, 2023	040093
California:						
Los Angeles	City of Malibu (23–09–0599P).	The Honorable Paul Grisanti, Mayor, City of Malibu, 23825 Stuart Ranch Road, Malibu, CA 90265.	City Hall, 23825 Stuart Ranch Road, Malibu, CA 90265.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 20, 2023	060745
Los Angeles	Unincorporated Areas of Los Angeles County (23–09–0599P).	The Honorable Janice Hahn, Chair, Board of Supervisors, Los Angeles County, 500 West Temple Street, Room 822, Los Angeles, CA 90012.	Los Angeles County Public Works Headquarters, Watershed Management Division, 900 South Fremont Avenue, Alhambra, CA 91803.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 20, 2023	065043
Riverside	City of Menifee (22–09–1724P).	The Honorable Bill Zimmerman, Mayor, City of Menifee, 29844 Haun Road, Menifee, CA 92586.	Public Works and Engineering Department, 29714 Haun Road, Menifee, CA 92586.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 20, 2023	060176
Riverside	City of Norco (22–09–1188P).	The Honorable Robin Grundmeyer, Mayor, City of Norco, 2870 Clark Avenue, Norco, CA 92860.	City Hall, 2870 Clark Avenue, Norco, CA 92860.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 13, 2023	060256
Riverside	City of Perris (22–09–1745P).	The Honorable Michael Vargas, Mayor, City of Perris, 101 North D Street, Perris, CA 92570.	Engineering Department, 24 South D Street, Suite 100, Perris, CA 92570.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 16, 2023	060258

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
San Bernardino.	City of Rancho Cucamonga (22–09–0746P).	The Honorable L. Dennis Michael, Mayor, City of Rancho Cucamonga, 10500 Civic Center Drive, Rancho Cucamonga, CA 91730.	City Hall, Engineering Department Plaza Level, 10500 Civic Center Drive, Rancho Cucamonga, CA 91730.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 2, 2023	060671
San Bernardino.	Unincorporated Areas of San Bernardino County (21–09–1996P).	The Honorable Dawn Rowe, Chair, Board of Supervisors, San Bernardino County, 385 North Arrowhead Avenue, 5th Floor, San Bernardino, CA 92415.	San Bernardino County Public Works, Water Resources Department, 825 East 3rd Street, San Bernardino, CA 92415.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 11, 2023	060270
San Diego	Unincorporated Areas of San Diego County (23–09–0045P).	The Honorable Nora Vargas, Chair, Board of Supervisors, San Diego County, 1600 Pacific Highway, Room 335, San Diego, CA 92101.	San Diego County Flood Control District, Department of Public Works, 5510 Overland Avenue, Suite 410, San Diego, CA 92123.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 2, 2023	060284
Florida:						
Bay	City of Panama City Beach (22–04–3762P).	The Honorable Mark Sheldon, Mayor, City of Panama City Beach, City Hall, 17007 Panama City Beach Parkway, Panama City Beach, FL 32413.	City Hall, 110 South Arnold Road, Panama City Beach, FL 32413.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 25, 2023	120013
Bay	Unincorporated Areas of Bay County (22–04–3762P).	Philip Griffitts, Chair, Board of Bay County Commissioners, 840 West 11th Street, Panama City, FL 32401.	Bay County Planning and Zoning, 707 Jenks Avenue, Suite B, Panama City, FL 32401.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 25, 2023	120004
Clay	Unincorporated Areas of Clay County (23–04–0201P).	Howard Wanamaker, County Manager, Clay County, P.O. Box 1366, Green Cove Springs, FL 32043.	Clay County, Public Works Department, 5 Esplanade Avenue, Green Cove Springs, FL 32043.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 20, 2023	120064
Illinois:						
Cook	City of Oak Forest (22–05–2765P).	The Honorable Henry Kuspa, Mayor, City of Oak Forest, 15440 South Central Avenue, Oak Forest, IL 60452.	City Hall, 15440 South Central Avenue, Oak Forest, IL 60452.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 23, 2023	170136
Cook	Unincorporated Areas of Cook County (20–05–1896P).	Toni Preckwinkle, President, Cook County Board of Commissioners, 118 North Clark Street, Room 537, Chicago, IL 60602.	Cook County Building and Zoning Department, 69 West Washington Street, 28th Floor, Chicago, IL 60602.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 6, 2023	170054
Cook	Unincorporated Areas of Cook County (22–05–2765P).	Toni Preckwinkle, President, Cook County Board of Commissioners, 118 North Clark Street, Room 537, Chicago, IL 60602.	Cook County Building and Zoning Department, 69 West Washington Street, 28th Floor, Chicago, IL 60602.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 23, 2023	170054
Cook	Village of Richton Park (20–05–1896P).	Rick Reinbold, Village President, Village of Richton Park, 4455 Sauk Trail, Richton Park, IL 60471.	Municipal Building, 4455 Sauk Trail, Richton Park, IL 60471.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 6, 2023	170149
Lake	Village of Mundelein (23–05–0305P).	The Honorable Steve Lentz, Mayor, Village of Mundelein, 300 Plaza Circle, Mundelein, IL 60060.	Village Hall, 300 Plaza Circle, Mundelein, IL 60060.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 10, 2023	170382
Lake	Village of Vernon Hills (23–05–0305P).	Roger Byrne, Village President, Village of Vernon Hills, 290 Evergreen Drive, Vernon Hills, IL 60061.	Village Hall, 290 Evergreen Drive, Vernon Hills, IL 60061.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 10, 2023	170394
Indiana:						
Allen	City of Fort Wayne (22–05–1754P).	The Honorable Tom Henry, Mayor, City of Fort Wayne, City Hall, 200 East Berry Street, Suite 470, Fort Wayne, IN 46802.	Department of Planning Services, 200 East Berry Street, Suite 150, Fort Wayne, IN 46802.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 5, 2023	180003

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Allen	Unincorporated Areas of Allen County (22–05–1754P).	F. Nelson Peters, Commissioner, Allen County Board of Commissioners, Citizens Square, 200 East Berry Street, Suite 410, Fort Wayne, IN 46802.	Allen County Department of Planning Services, 200 East Berry Street, Suite 150, Fort Wayne, IN 46802.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 5, 2023	180302
Kansas:						
Johnson	City of Shawnee (22–07–1041P).	The Honorable Michelle Distler, Mayor, City of Shawnee, City Hall, 11110 Johnson Drive, Shawnee, KS 66203.	City Hall, 11110 Johnson Drive, Shawnee, KS 66203.	*https://msc.fema.gov/portal/advanceSearch.*	Aug. 30, 2023	200177
Michigan:						
Oakland	City of Troy (23–05–0001P).	The Honorable Ethan Baker, Mayor, City of Troy, 500 West Big Beaver Road, Troy, MI 48084.	City Hall, 500 West Big Beaver Road, Troy, MI 48084.	*https://msc.fema.gov/portal/advanceSearch.*	Sep. 22, 2023	260180
Minnesota:						
Dakota	Unincorporated Areas of Dakota County (22–05–3188P).	Matt Smith, Manager, Dakota County, 1590 Highway 55, Hastings, MN 55033.	Dakota County Administration Center, 1590 Highway 55, Hastings, MN 55033.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 30, 2023	270101
Nevada:						
Clark	City of North Las Vegas (23–09–0579P).	The Honorable Pamela Goynes-Brown, Mayor, City of North Las Vegas, 2250 Las Vegas Boulevard North, Suite 910, North Las Vegas, NV 89030.	Public Works Department, 2250 Las Vegas Boulevard North, Suite 200, North Las Vegas, NV 89030.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 18, 2023	320007
New Jersey:						
Monmouth	Township of Neptune (22–02–0510P).	The Honorable Keith Cafferty, Mayor, Township of Neptune, P.O. Box 1125, Neptune, NJ 07754.	Township Hall, Construction Department, 25 Neptune Boulevard, Neptune, NJ 07753.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 19, 2023	340317
Monmouth	Township of Wall (22–02–0510P).	The Honorable Timothy J. Farrell, Mayor, Township of Wall, 2700 Allaire Road, Wall, NJ 07719.	Township Hall, Municipal Building, 2700 Allaire Road, Wall, NJ 07719.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 19, 2023	340333
Oregon:						
Washington	City of Beaverton (22–10–0942P).	The Honorable Lacey Beaty, Mayor, City of Beaverton, 12725 Southwest Millikan Way, 5th Floor, Beaverton, OR 97076.	Community Development Department, 12725 Southwest Millikan Way, Beaverton, OR 97076.	*https://msc.fema.gov/portal/advanceSearch.*	Sep. 29, 2023	410240
Virginia:						
Independent City.	City of Virginia Beach (22–03–0299P).	The Honorable Robert Dyer, Mayor, City of Virginia Beach, City Hall, 2401 Courthouse Drive, Building #1, Virginia Beach, VA 23456.	Department of Public Works, 2405 Courthouse Drive, Building 1, Municipal Center Building #2, Virginia Beach, VA 23456.	*https://msc.fema.gov/portal/advanceSearch.*	Sep. 27, 2023	515531
Wisconsin:						
Brown	Unincorporated Areas of Brown County (20–05–4610P).	Patrick Buckley, Chair, Brown County Board of Supervisors, 305 East Walnut Street, Green Bay, WI 54305.	Brown County Office Northern Building, 305 East Walnut Street, Room 320, Green Bay, WI 54301.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 31, 2023	550020

[FR Doc. 2023–16743 Filed 8–4–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6407–N–01]

Public Interest, General Applicability Waiver of Build America, Buy America Provisions as Applied to Pacific Island/Territory Recipients of HUD Federal Financial Assistance

AGENCY: Office of the Secretary, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: In accordance with the Build America, Buy America Act (BABA), this notice advises that HUD is proposing a public interest, general applicability waiver for a period of 18 months to the Buy America Domestic Content Procurement Preference (''Buy America Preference,'' or ''BAP'') as applied to Federal Financial Assistance (''FFA'') used for infrastructure projects in the Commonwealth of Northern Mariana Islands (''CNMI''), Guam, American Samoa, (hereinafter collectively ''Pacific Island/Territory Communities''). In the case of FFA obligated by HUD through its Community Development Block Grant (CDBG) programs on or after November 15, 2022, but prior to the effective date of the final waiver, the waiver applies to all expenditures incurred on or after the effective date of the final waiver up until the limited period of 18 months. For expenditures incurred on or after the effective date of the final waiver, the waiver applies both to funds obligated by HUD on or after the effective date of the final waiver and any expenditures up and until 18 months from the effective date of the final waiver.

DATES: HUD published this proposed waiver for public comment on its website on August 2, 2023. Pursuant to section 70914(c)(2) of BABA, HUD is required to solicit comments from the public on this proposed waiver. As a matter of policy, HUD has elected to provide the public with an opportunity to comment for an extended period of thirty days from the date published on HUD's web page in this instance. Comments on the proposed waiver set out in this document are due on or before September 1, 2023. HUD will consider comments received in response to this Notice and announce its determination with respect to the adoption of this notice, including any changes that may be made in response to comments through a subsequent Notice.

ADDRESSES: Interested persons are invited to submit comments on the general applicability waiver. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov*. To receive consideration as public comments, comments must be submitted through one of two methods, specified below. All submissions must refer to the above docket number and title.

1. Electronic Submission of Comments. Interested/persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov*. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

2. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

No Facsimile Comments. Facsimile (FAX) comments will not be accepted.

Public Inspection of Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the submissions must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs*. Copies of all submissions are available for inspection and downloading at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Faith Rogers, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10126, Washington, DC 20410–5000, at (202) 402–7082 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs*. HUD encourages submission of questions about this document be sent to *BuildAmericaBuyAmerica@hud.gov*.

SUPPLEMENTARY INFORMATION:

I. Build America, Buy America

The Build America, Buy America Act (''BABA'' or ''the Act'') was enacted on November 15, 2021, as part of the Infrastructure Investment and Jobs Act (''IIJA'') (Pub. L. 117–58). The Act establishes a domestic content procurement preference, the BAP, for Federal infrastructure programs. Section 70914(a) of the Act establishes that no later than 180 days after the date of enactment, HUD must ensure that none of the funds made available for infrastructure projects may be obligated by the Department unless it has taken steps to ensure that the iron, steel, manufactured products, and construction materials used in a project are produced in the United States. In section 70912, the Act further defines a project to include ''the construction, alteration, maintenance, or repair of infrastructure in the United States'' and includes within the definition of infrastructure those items traditionally included along with buildings and real property. Thus, starting May 14, 2022, new awards of HUD FFA, and any of those funds newly obligated by HUD then obligated by the grantee for infrastructure projects, are covered under BABA provisions of the Act, 41 U.S.C. 8301 note, unless covered by a waiver.

II. HUD's Progress in Implementation of the Act Generally

Since the enactment of the Act, HUD has worked diligently to develop a plan to fully implement the BAP across its FFA programs. HUD understands that advancing Made in America objectives is a continuous effort and believes setting forth a transparent schedule of future implementation for FFA programs provides recipients, stakeholders, and industry partners with the time and notice necessary to efficiently and effectively implement the BAP in Pacific Island/Territory Communities.[1] Additionally, HUD

[1] Pursuant to 42 U.S.C. 5302(a)(24)(24), the term ''insular area'' means each of Guam, the Northern

Continued

understands that similar to Tribal FFA Recipients, Pacific Island/Territory Communities have significant complications accessing construction materials, manufactured products, and steel needed for infrastructure projects. HUD recently announced plans to move forward with the implementation of the new BAP requirements in connection with its award of FFA to non-Tribal Recipients in a manner designed to maximize coordination and collaboration to support long-term investments in domestic production. HUD continues its efforts to implement the Act in those programs consistent with the guidance and requirements of the Made in America Office of the Office of Management and Budget, including guidance concerning compliance with the BAP.

In order to ensure orderly implementation of the BAP across HUD's FFA programs awarding funds to non-Tribal Recipients, HUD has provided public interest, general applicability waivers in order to implement the BAP in phases in connection with the application of the BAP in such programs and announced a corresponding implementation plan. As part of those efforts, HUD has published two general applicability, public interest waivers covering Exigent Circumstances and De Minimis and Small Grants, which can be found at *https://www.hud.gov/program_offices/general_counsel/BABA*.

Additionally, HUD proposes that it is in the public interest to waive the BABA requirements for FFA awarded for infrastructure projects in Pacific Island/Territory Communities while HUD works to gather more information on supply chains, costs, and impacts. This proposed waiver is critical to provide the time for HUD to collect and analyze evidence to determine if a more targeted waiver of the BAP requirements is in the public interest. The waiver would also allow time for HUD to offer technical assistance to reduce the administrative burden to recipients for projects in the remote Pacific Island/Territory Communities were complying with the domestic sourcing requirements in BABA presents challenges. HUD is concerned that failure to provide these remote communities with flexibilities could perpetuate systemic barriers to opportunities and benefits and limit HUD's ability to deliver resources and benefits equitably to all in these Pacific Island/Territory Communities.

Mariana Islands, the Virgin Islands, and American Samoa. As proposed, this waiver would only be applicable for CNMI, Guam, American Samoa, if made final.

Additionally, HUD may need to dedicate significant staff and contractor time to assist extremely remote Pacific Island/Territory Communities with implementing preference requirements for the first time and to support the increased workload to process project-specific waivers. As such, HUD is interested in determining if these concerns justify a targeted waiver and whether its initial assessment may or may not be borne out by evidence.

III. Waivers

Under section 70914(b), HUD and other Federal agencies have authority to waive the application of a domestic content procurement preference when (1) application of the preference would be contrary to the public interest, (2) the materials and products subject to the preference are not produced in the United States at a sufficient and reasonably available quantity or satisfactory quality, or (3) inclusion of domestically produced materials and products would increase the cost of the overall project by more than 25 percent. Section 70914(c) provides that a waiver under section 70914(b) must be published by the agency with a detailed written explanation for the proposed determination and provide an appropriate public comment period of 15 or 30 days depending on the substance of the waiver.

IV. Pacific Island/Territory Infrastructure and HUD Programs

Many Pacific Island/Territory Communities still lack basic infrastructure such as roads, running water, and indoor plumbing. The need for safe, decent, and sanitary housing is immense. For example, the Northern Marianas are very far away from the U.S. Mainland. This will create challenges with HUD providing technical assistance and monitoring the use of the funds. It is also a place with very different rules than the U.S. Mainland and is much more connected to Asia than to the U.S. Mainland. Standard products that are absolute necessities in the Pacific Island/Territory Communities, like typhoon-rated glass windows and aluminum shutters, also cost significantly more if sourced domestically. For example, representatives of Pacific Island/Territory communities stated, ''the cost of aluminum is double if sourced from the U.S. Mainland'' and ''The shipping cost from Korea or Asia for a 20-footer container is $3,000 but shipping from the mainland United States is about $12,000.''

HUD is aware that substantial changes to shipping and supply chains to incorporate domestic sourcing requirements for infrastructure projects in Pacific Island/Territory Communities could take multiple years to establish. For example, these economies have few local heavy manufacturers and largely rely on established regional supply chains from the Philippines. With the distance of economies in the Pacific Island/Territory Communities, these communities must import products via air or sea. Most goods, equipment, materials, and supplies are imported and rely on shipping with associated timelines and unpredictable shipping fuel cost fluctuations. Moreover, materials sourced from the United States lead to additional shipping fees and longer lead times, thus significantly extending construction activity schedules. Lastly, ongoing gaps in supply chain availability impact lead times for materials, increasing project timelines. For these reasons, HUD is concerned that requiring compliance with the domestic sourcing requirements in BABA at this time may increase already elevated project completion times and costs—particularly in the short run—and seeks time to better understand the local manufacturing footprint and the balance of equities for residents of the Pacific Island/Territory Communities.

For example, HUD Community Planning and Development Formula Program Allocations for Pacific Island/Territory Communities include Community Development Block Grant, HOME, Emergency Solutions Grant (''ESG''), Housing Opportunities for Persons With AIDS Program (''HOPWA''), and Housing Trust Fund (''HTF''). As shown below, there are HUD CDBG formula grant recipients that are subject to the BAP pursuant to HUD's Public Interest Phased Implementation Waiver of Build America, Buy America Provisions as Applied to Recipients of HUD Federal Financial Assistance, for the purchase of iron or steel products in infrastructure projects funded by CDBG formula grants obligated by HUD on or after November 15, 2022. For HOME and HTF, BABA applicability will be in effect for funds obligated by HUD on or after August 23, 2024. For all other HUD FFA including ESG and HOPWA, BABA applicability will be in effect for FFA used to purchase iron and steel used in infrastructure projects for funds obligated by HUD on February 22, 2024. Subsequently, BABA applicability will be in effect for HUD FFA obligated on or after August 23, 2024, for construction materials and manufactured products. Therefore,

without a waiver, HUD FFA used in Pacific Island/Territory Communities for infrastructure projects will be subject to the BAP.[2]

FY 2023 Community Planning and Development Formula Program Allocations

Name	STA	CDBG	HOME	ESG	HOPWA	HTF
American Samoa	AS	$1,029,433	$298,791	$85,296	$0	$0
Guam	GU	3,185,755	1,256,171	263,963	0	157,106.91
Northern Mariana Islands	MP	980,125	489,268	81,210	0	76,533.43

FY 2023 Public and Indian Housing Program Allocations

Name	STA	Operating fund	Capital funds	Section 8
Guam	GU	$5.33 million	$3.2 million	$38.3 million.
Northern Mariana Islands	MP	$0	$0	$3.3 million.

Additionally, the Public and Indian Housing (''PIH'') Program Allocations for Pacific Island/Territory Communities include the Guam Housing & Urban Renewal Authority in Guam and the Northern Marianas Housing Corporation in the Northern Marianas islands. Pursuant to the phased implementation waiver, BABA applicability will be in effect for funds obligated by HUD on or after August 23, 2024, for public housing FFA used to purchase iron and steel, construction materials, and manufactured products for maintenance projects.

The above-named programs are critical because they allow HUD to support affordable housing and infrastructure needs in these specific Pacific Island/Territory Communities—particularly for the benefit of low- and moderate-income families. As of November 15, 2022, the BAP applies to CDBG formula grants used to purchase iron and steel for infrastructure projects. Accordingly, HUD must ensure that Pacific Island/Territory Recipients are able to effectively implement the BAP in a manner that ensures that the purposes of BABA are carried out, while at the same time preventing additional undue barriers to the development of Pacific Island/Territory infrastructure, which has suffered from decades of underinvestment.

HUD has determined that additional time is needed to fully assess the impacts that the BAP will have on Pacific Island/Territory Recipients and to plan for the efficient and orderly implementation of the BAP, as appropriate. HUD is particularly interested in developing a specifically tailored waiver based on stakeholder and Pacific Island/Territory Recipient feedback regarding the impact of the BAP on infrastructure projects that are funded under HUD's various Pacific Island/Territory programs. With the benefit of HUD's recently published phased implementation waiver and Tribal consultation waiver extension, HUD needs additional time to seek feedback from Pacific Island/Territory Communities and funding recipients on whether and when HUD should take a similar phased approach with respect to the implementation of the BAP under its Pacific Island/Territory programs. HUD will also assess the unique and diverse conditions of Pacific Island/Territory Communities across the country and determine how the BAP should be applied after taking those conditions into account.

V. Public Interest in a General Applicability Waiver of Buy America Provisions for Pacific Island/Territory Recipients

In this Notice, HUD is seeking comment on a new limited, 18-month public interest, general applicability waiver of the BAP in connection with HUD's FFA used for infrastructure in Pacific Island/Territory Communities to provide the Department with sufficient information to successfully implement BABA. Infrastructure is an eligible activity under some of the above-named programs and will be subject to the BAP. Because the application of BAP mandated by the Act is new to all HUD FFA for Pacific Island/Territory infrastructure projects, HUD needs additional time to engage Pacific Island/Territory Communities about the application of the BAP for Pacific Island/Territory projects—particularly with the distance from economies, it is imperative to determine how the BAP should be effectively applied to HUD's various FFA for Pacific Island/Territory projects, how the BAP should be phased in to allow for successful implementation, and how compliance will be verified—all in a way to enhance infrastructure projects in these areas. As such, there is a significant need for HUD to further engage with Pacific Island/Territory Recipients. HUD now has the benefit of having fully considered an appropriate method of phased implementation across its other FFA programs and has begun the methodical implementation of the BAP in those other FFA programs. At the same time, HUD has determined that it is in the public's interest to not apply the BAP to FFA awarded for infrastructure projects in Pacific Island/Territory Communities prior to additional engagement.

VI. Planned Pacific Island/Territory Engagement

Based on HUD's observations about disaster recovery for three 2018 disasters in the Pacific—American Samoa's recovery from Cyclone Gita and the most severe disaster—Typhoon's Mangkhut and Super Typhoon Yutu in the Northern Marianas, it is necessary for HUD to solicit feedback from Pacific Island/Territory Communities on other related issues, including how to effectively implement the BAP for extremely remote communities, such as the American Samoa. For example, the Northern Marianas is comprised of fifteen islands, three of them that are populated. Of the three, the most populated is Saipan (population 48,220), the nearby Tinian (3,136), and Rota (2,527), which is closer to Guam than it is to Saipan. Much different than American Samoa, the Northern Marianas are connected to Asia—two to four hours of flying to get to Asia is closer than anywhere on the U.S. Mainland except Guam. HUD acknowledges that Pacific Island/

[2] See *https://www.hud.gov/program_offices/comm_planning/budget.*

Territory Communities have major concerns about availability of American-made products from the U.S. Mainland and continue to struggle with challenges because of their distance away from main supply sources. Pacific Island/Territory Communities are already facing major challenges with accessing construction materials, and major cost overruns due to a lack of available materials—particularly in remote Pacific Island/Territory Communities.

During the 18-month waiver period, HUD will thoroughly engage Pacific Island/Territory housing practitioners, stakeholders, and FFA recipients. HUD will do so by soliciting written feedback from Pacific Island/Territory Communities and stakeholders specifically addressing the impact of the BAP on HUD's Pacific Island/Territory programs. After engaging and receiving feedback, HUD will seek to implement the BAP in a manner that advances the Made in America objectives while also ensuring that the BAP implementation does not serve as a major barrier to Pacific Island/Territory Communities' efforts to develop critical infrastructure. HUD will implement the BAP in a thoughtful manner that ensures that Pacific Island/Territory Recipients can effectively implement the BAP without substantial negative impacts on planned and ongoing critical infrastructure projects. HUD will also seek to provide additional technical assistance resources to ensure that Pacific Island/Territory Recipients can build capacity and be in a better position to comply with the BAP.

VII. Assessment of Cost Advantage of a Foreign-Sourced Product

Under OMB Memorandum M–22–11, ''Memorandum for Heads of Executive Departments and Agencies,'' published on April 18, 2022, agencies are expected to assess ''whether a significant portion of any cost advantage of a foreign-sourced product is the result of the use of dumped steel, iron, or manufactured products or the use of injuriously subsidized steel, iron, or manufactured products'' as appropriate before granting a public interest waiver. HUD's analysis has concluded that this assessment is not applicable to this waiver, as this waiver is not based on the cost of foreign-sourced products.

VIII. Limited Duration of the Waiver

HUD remains committed to the successful implementation of the important BAP across its programs providing covered FFA for infrastructure projects, while recognizing the unique needs and geographically related challenges of Pacific Island/Territory Communities. HUD is committed to engaging with Island/Territory Communities, stakeholders, and FFA recipients as noted above to further this goal.

IX. Solicitation of Comments

HUD is soliciting comment from the public on the proposed waiver described in this Notice for a period of 30 days from the date of publication on HUD's web page. If issued, this waiver will be applicable to Pacific Island/Territory FFA that HUD obligates on or after the effective date of the final waiver and in connection with the expenditure of FFA, which had been previously obligated by HUD, throughout the applicable waiver period.

Dated: August 2, 2023.

Marcia L. Fudge,

Secretary.

[FR Doc. 2023–16798 Filed 8–4–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6409–N–01]

Mortgage and Loan Insurance Programs Under the National Housing Act—Debenture Interest Rates

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: This Notice announces changes in the interest rates to be paid on debentures issued with respect to a loan or mortgage insured by the Federal Housing Administration under the provisions of the National Housing Act (the Act). The interest rate for debentures issued under the Act during the 6-month period beginning July 1, 2023, is 3½ percent. The interest rate for debentures issued under any other provision of the Act is the rate in effect on the date that the commitment to insure the loan or mortgage was issued, or the date that the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. The interest rate for debentures issued under these other provisions with respect to a loan or mortgage committed or endorsed during the 6-month period beginning July 1, 2023, is 3⅞ percent.

FOR FURTHER INFORMATION CONTACT: Elizabeth Olazabal, Department of Housing and Urban Development, 451 Seventh Street SW, Room 5146, Washington, DC 20410–8000; telephone (202) 402–4608 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Section 224 of the National Housing Act (12 U.S.C. 1715o) provides that debentures issued under the Act with respect to an insured loan or mortgage (except for debentures issued pursuant to section 221(g)(4) of the Act) will bear interest at the rate in effect on the date the commitment to insure the loan or mortgage was issued, or the date the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. This provision is implemented in HUD's regulations at 24 CFR 203.405, 203.479, 207.259(e)(6), and 220.830. These regulatory provisions state that the applicable rates of interest will be published twice each year as a notice in the **Federal Register**.

Section 224 further provides that the interest rate on these debentures will be set from time to time by the Secretary of HUD, with the approval of the Secretary of the Treasury, in an amount not in excess of the annual interest rate determined by the Secretary of the Treasury pursuant to a statutory formula based on the average yield of all outstanding marketable Treasury obligations of maturities of 15 or more years.

The Secretary of the Treasury (1) has determined, in accordance with the provisions of section 224, that the statutory maximum interest rate for the period beginning July 1, 2023, is 3⅞ percent; and (2) has approved the establishment of the debenture interest rate by the Secretary of HUD at 3⅞ percent for the 6-month period beginning July 1, 2023. This interest rate will be the rate borne by debentures issued with respect to any insured loan or mortgage (except for debentures issued pursuant to section 221(g)(4)) with insurance commitment or endorsement date (as applicable) within the next 6 months of 2023).

For convenience of reference, HUD is publishing the following chart of debenture interest rates applicable to mortgages committed or endorsed since January 1, 1980:

Effective interest rate	On or after	Prior to
9½	Jan. 1, 1980	July 1, 1980.
9⅞	July 1, 1980	Jan. 1, 1981.
11¾	Jan. 1, 1981	July 1, 1981.
12⅞	July 1, 1981	Jan. 1, 1982.
12¾	Jan. 1, 1982	Jan. 1, 1983.
10¼	Jan. 1, 1983	July 1, 1983.

Effective interest rate	On or after	Prior to
10⅜	July 1, 1983	Jan. 1, 1984.
11½	Jan. 1, 1984	July 1, 1984.
13⅜	July 1, 1984	Jan. 1, 1985.
11⅝	Jan. 1, 1985	July 1, 1985.
11⅛	July 1, 1985	Jan. 1, 1986.
10¼	Jan. 1, 1986	July 1, 1986.
8¼	July 1, 1986	Jan. 1. 1987.
8	Jan. 1, 1987	July 1, 1987.
9	July 1, 1987	Jan. 1, 1988.
9⅛	Jan. 1, 1988	July 1, 1988.
9⅜	July 1, 1988	Jan. 1, 1989.
9¼	Jan. 1, 1989	July 1, 1989.
9	July 1, 1989	Jan. 1, 1990.
8⅛	Jan. 1, 1990	July 1, 1990.
9	July 1, 1990	Jan. 1, 1991.
8¾	Jan. 1, 1991	July 1, 1991.
8½	July 1, 1991	Jan. 1, 1992.
8	Jan. 1, 1992	July 1, 1992.
8	July 1, 1992	Jan. 1, 1993.
7¾	Jan. 1, 1993	July 1, 1993.
7	July 1, 1993	Jan. 1, 1994.
6⅝	Jan. 1, 1994	July 1, 1994.
7¾	July 1, 1994	Jan. 1, 1995.
8⅜	Jan. 1, 1995	July 1, 1995.
7¼	July 1, 1995	Jan. 1, 1996.
6½	Jan. 1, 1996	July 1, 1996.
7¼	July 1, 1996	Jan. 1, 1997.
6¾	Jan. 1, 1997	July 1, 1997.
7⅛	July 1, 1997	Jan. 1, 1998.
6⅜	Jan. 1, 1998	July 1, 1998.
6⅛	July 1, 1998	Jan. 1, 1999.
5½	Jan. 1, 1999	July 1, 1999.
6⅛	July 1, 1999	Jan. 1, 2000.
6½	Jan. 1, 2000	July 1, 2000.
6½	July 1, 2000	Jan. 1, 2001.
6	Jan. 1, 2001	July 1, 2001.
5⅞	July 1, 2001	Jan. 1, 2002.
5¼	Jan. 1, 2002	July 1, 2002.
5¾	July 1, 2002	Jan. 1, 2003.
5	Jan. 1, 2003	July 1, 2003.
4½	July 1, 2003	Jan. 1, 2004.
5⅛	Jan. 1, 2004	July 1, 2004.
5½	July 1, 2004	Jan. 1, 2005.
4⅞	Jan. 1, 2005	July 1, 2005.
4½	July 1, 2005	Jan. 1, 2006.
4⅞	Jan. 1, 2006	July 1, 2006.
5⅜	July 1, 2006	Jan. 1, 2007.
4¾	Jan. 1, 2007	July 1, 2007.
5	July 1, 2007	Jan. 1, 2008.
4½	Jan. 1, 2008	July 1, 2008.
4⅝	July 1, 2008	Jan. 1, 2009.
4⅛	Jan. 1, 2009	July 1, 2009.
4⅛	July 1, 2009	Jan. 1, 2010.
4¼	Jan. 1, 2010	July 1, 2010.
4⅛	July 1, 2010	Jan. 1, 2011.
3⅞	Jan. 1, 2011	July 1, 2011.
4⅛	July 1, 2011	Jan. 1, 2012.
2⅞	Jan. 1, 2012	July 1, 2012.
2¾	July 1, 2012	Jan. 1, 2013.
2½	Jan. 1, 2013	July 1, 2013.
2⅞	July 1, 2013	Jan. 1, 2014.
3⅝	Jan. 1, 2014	July 1, 2014.
3¼	July 1, 2014	Jan. 1, 2015.
3	Jan. 1, 2015	July 1, 2015.
2⅞	July 1, 2015	Jan. 1, 2016.
2⅞	Jan. 1, 2016	July 1, 2016.
2½	July 1, 2016	Jan. 1, 2017.
2¾	Jan. 1, 2017	July 1, 2017.
2⅞	July 1, 2017	Jan. 1, 2018.
2¾	Jan. 1, 2018	July 1, 2018.
3⅛	July 1, 2018	Jan. 1, 2019.
3⅜	Jan 1, 2019	July 1, 2019.
2¾	July 1, 2019	Jan 1, 2020.
2¼	Jan 1, 2020	July 1, 2020.
1¼	July 1, 2020	Jan. 1, 2021.
1⅜	Jan 1, 2021	July 1, 2021.
2¼	July, 1 2021	Jan 1, 2022.
1⅞	Jan 1, 2022	July 1, 2022.
3¼	July 1,2022	Jan 1, 2023.
4¼	Jan 1, 2023	July 1, 2023.
3⅞	July 1, 2023	Jan 1, 2024.

Section 215 of Division G, Title II of Public Law 108–199, enacted January 23, 2004 (HUD's 2004 Appropriations Act) amended section 224 of the Act, to change the debenture interest rate for purposes of calculating certain insurance claim payments made in cash. Therefore, for all claims paid in cash on mortgages insured under section 203 or 234 of the National Housing Act and endorsed for insurance after January 23, 2004, the debenture interest rate will be the monthly average yield, for the month in which the default on the mortgage occurred, on United States Treasury Securities adjusted to a constant maturity of 10 years, as found in Federal Reserve Statistical Release H–15. The Federal Housing Administration has codified this provision in HUD regulations at 24 CFR 203.405(b) and 24 CFR 203.479(b).

Similarly, section 520(a) of the National Housing Act (12 U.S.C. 1735d) provides for the payment of an insurance claim in cash on a mortgage or loan insured under any section of the National Housing Act before or after the enactment of the Housing and Urban Development Act of 1965. The amount of such payment shall be equivalent to the face amount of the debentures that would otherwise be issued, plus an amount equivalent to the interest which the debentures would have earned, computed to a date to be established pursuant to regulations issued by the Secretary. The implementing HUD regulations for multifamily insured mortgages at 24 CFR 207.259(e)(1) and (e)(6), when read together, provide that debenture interest on a multifamily insurance claim that is paid in cash is paid from the date of the loan default at the debenture rate in effect at the time of commitment or endorsement (or initial endorsement if there are two or more endorsements) of the loan, whichever is higher.

Section 221(g)(4) of the Act provides that debentures issued pursuant to that paragraph (with respect to the assignment of an insured mortgage to the Secretary) will bear interest at the ''going Federal rate'' in effect at the time the debentures are issued. The term ''going Federal rate'' is defined to mean the interest rate that the Secretary of the Treasury determines, pursuant to a statutory formula based on the average yield on all outstanding marketable Treasury obligations of 8- to 12-year maturities, for the 6-month periods of January through June and July through December of each year. Section 221(g)(4) is implemented in the HUD regulations at 24 CFR 221.255 and 24 CFR 221.790.

The Secretary of the Treasury has determined that the interest rate to be borne by debentures issued pursuant to section 221(g)(4) during the 6-month period beginning July 1, 2023, is 3 ½ percent. The subject matter of this notice falls within the categorical exemption from HUD's environmental clearance procedures set forth in 24 CFR 50.19(c)(6). For that reason, no environmental finding has been prepared for this notice.

(Authority: Sections 211, 221, 224, National Housing Act, 12 U.S.C. 1715b, 1715l, 1715o; section 7(d), Department of HUD Act, 42 U.S.C. 3535(d).)

Julia Gordon,

Assistant Secretary for Housing, Federal Housing Commissioner.

Effective interest rate	On or after	Prior to	221(g)(4)
3.875	July 1, 2023	January 1, 2024	3.500
4.250	January 1, 2023	July 1, 2023	3.875
3.250	July 1, 2022	January 1, 2023	2.875
1.875	January 1, 2022	July 1, 2022	1.500
2.250	July 1, 2021	January 1, 2022	1.500
1.375	January 1, 2021	July 1, 2021	0.750
1.250	July 1, 2020	January 1, 2021	0.625
2.250	January 1, 2020	July 1, 2020	1.750
2.750	July 1, 2019	January 1, 2020	2.375
3.375	January 1, 2019	July 1, 2019	3.125
3.125	July 1, 2018	January 1, 2019	3.000

Effective interest rate	On or after	Prior to	221(g)(4)
2.750	January 1, 2018	July 1, 2018	2.375
2.875	July 1, 2017	January 1, 2018	2.250
2.750	January 1, 2017	July 1, 2017	2.125
2.500	July 1, 2016	January 1, 2017	1.750
2.875	January 1, 2016	July 1, 2016	2.250
2.875	July 1, 2015	January 1, 2016	2.125
3.000	January 1, 2015	July 1, 2015	2.250
3.250	July 1, 2014	January 1, 2015	2.375
3.625	January 1, 2014	July 1, 2014	2.500
2.875	July 1, 2013	January 1, 2014	1.750
2.500	January 1, 2013	July 1, 2013	1.375
2.750	July 1, 2012	January 1, 2013	1.625
2.875	January 1, 2012	July 1, 2012	1.875
4.125	July 1, 2011	January 1, 2012	3.000
3.875	January 1, 2011	July 1, 2011	2.500
4.125	July 1, 2010	January 1, 2011	3.375
4.250	January 1, 2010	July 1, 2010	3.375
4.125	July 1, 2009	January 1, 2010	3.375
4.125	January 1, 2009	July 1, 2009	3.750
4.625	July 1, 2008	January 1, 2009	3.875
4.500	January 1, 2008	July 1, 2008	4.125
5.000	July 1, 2007	January 1, 2008	4.750
4.750	January 1, 2007	July 1, 2007	4.875
5.375	July 1, 2006	January 1, 2007	5.750
4.875	January 1, 2006	July 1, 2006	5.125
4.500	July 1, 2005	January 1, 2006	4.875
4.875	January 1, 2005	July 1, 2005	5.000
5.500	July 1, 2004	January 1, 2005	5.375
5.125	January 1, 2004	July 1, 2004	5.250
4.500	July 1, 2003	January 1, 2004	5.000
5.000	January 1, 2003	July 1, 2003	5.750
5.750	July 1, 2002	January 1, 2003	6.625
5.250	January 1, 2002	July 1, 2002	6.375
5.875	July 1, 2001	January 1, 2002	6.750
6.000	January 1, 2001	July 1, 2001	7.125
500	July 1, 2000	January 1, 2001	7.500
6.500	January 1, 2000	July 1, 2000	7.125
6.125	July 1, 1999	January 1, 2000	6.625
5.500	January 1, 1999	July 1, 1999	6.000
6.125	July 1, 1998	January 1, 1999	6.250
6.375	January 1, 1998	July 1, 1998	6.250
7.125	July 1, 1997	January 1, 1998	6.375
6.750	January 1, 1997	July 1, 1997	6.375
7.250	July 1, 1996	January 1, 1997	6.875
6.500	January 1, 1996	July 1, 1996	6.000
7.250	July 1, 1995	January 1, 1996	6.750
8.375	January 1, 1995	July 1, 1995	8.000
7.750	July 1, 1994	January 1, 1995	7.250
6.625	January 1, 1994	July 1, 1994	5.750
7.000	July 1, 1993	January 1, 1994	6.000
7.750	January 1, 1993	July 1, 1993	6.875
8.000	July 1, 1992	January 1, 1993	7.500
8.000	January 1, 1992	July 1, 1992	7.500
8.500	July 1, 1991	January 1, 1992	8.125
8.750	January 1, 1991	July 1, 1991	8.250
9.000	July 1, 1990	January 1, 1991	8.625
8.125	January 1, 1990	July 1, 1990	7.750
9.000	July 1, 1989	January 1, 1990	8.625
9.250	January 1, 1989	July 1, 1989	8.625
9.375	July 1, 1988	January 1, 1989	8.625
9.125	January 1, 1988	July 1, 1988	8.375
9.000	July 1, 1987	January 1, 1988	8.250
8.000	January 1, 1987	July 1,1987	7.000
8.250	July 1, 1986	January 1, 1987	7.500
10.250	January 1, 1986	July 1, 1986	9.250
11.125	July 1, 1985	January 1, 1986	10.125
11.625	January 1, 1985	July 1, 1985	10.625
13.375	July 1, 1984	January 1, 1985	12.000
11.500	January 1, 1984	July 1, 1984	10.500
10.375	July 1, 1983	January 1, 1984	9.375
10.250	January 1, 1983	July 1, 1983	9.750
12.750	July 1, 1982	January 1, 1983	12.500
12.750	January 1, 1982	July 1, 1982	11.625
12.875	July 1, 1981	January 1, 1982	11.625

Effective interest rate	On or after	Prior to	221(g)(4)
11.750	January 1, 1981	July 1, 1981	10.875
9.875	July 1, 1980	January 1, 1981	9.375
9.500	January 1, 1980	July 1, 1980	

[FR Doc. 2023–16738 Filed 8–4–23; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SLBE–NPS0035739; PPMWSLBES0; PPMPSPD1Z.YM0000; OMB Control Number 1024–NEW]

Agency Information Collection Activities; Sleeping Bear Dunes National Lakeshore Visitor Use Management Study

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 we, the National Park Service (NPS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before October 6, 2023.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to the NPS Information Collection Clearance Officer (ADIR–ICCO), 13461 Sunrise Valley Drive, (MS–244) Reston, VA 20191 (mail); or *phadrea_ponds@nps.gov* (email). Please reference Office of Management and Budget (OMB) Control Number ''1024–NEW (Sleeping Bear)'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Thomas A. Ulrich, Deputy Superintendent, Sleeping Bear Dunes National Lakeshore at *tom_ulrich@nps.gov* (email) or at 231–326–4703 (telephone). Please reference OMB Control Number 1024–NEW (Sleeping Bear) in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) is the collection necessary to the proper functions of the NPS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The National Park Service (NPS) is authorized by 54 U.S.C. 100701 to collect information that will improve the ability of the NPS to provide management, protection, and interpretation of, and research on, the resources of the System. Sleeping Bear Dunes National Lakeshore is a 71,199-acre NPS unit that preserves natural features for the benefit of the public.

The park's 2009 General Management Plan identified areas of importance and concern, including congestion in certain areas and the preservation of designated wilderness areas. Data from a 2012–2013 visitor survey suggested that social encounters would likely increase and negatively affect social and resource conditions. Since 2013, visitation to the park has increased by over 25%, and 32,550 acres of the park are now federally designated wilderness. Park managers are seeking data on current social and resource conditions to guide decisions to maintain and enhance visitor experiences.

This study will provide information on visitor use patterns and user characteristics during the busy summer season. The expected outcomes of this study are to:

- Provide updated information on visitor use patterns, motivations, and preferences across the park.
- Examine visitor attitudes toward management strategies and actions addressing visitor use.
- Provide information for use in future planning efforts (*e.g.,* river use plans, management plan updates).

Results from this study will be used by park managers to target resources to inform strategic planning efforts and infrastructure improvements, update visitor services and amenities, and determine appropriate staffing levels.

Title of Collection: Sleeping Bear Dunes National Lakeshore Visitor Use Management Study.

OMB Control Number: 1024–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 2,400.

Estimated Completion Time per Response: 13 minutes.

Total Estimated Number of Annual Burden Hours: 520 Hrs.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor nor is a person required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2023–16799 Filed 8–4–23; 8:45 am]
BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRSS–PPWONRADC0; PPMRSNR1Y.NM0000; 222P103601; OMB Control Number 1024–NEW]

Agency Information Collection Activities; Visitor Perceptions of Climate Change Study

AGENCY: National Park Service, Interior.

ACTION: Notice of information collections; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 we, the National Park Service (NPS), are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2023.

ADDRESSES: Written comments and suggestions on the information collection requirements should be submitted by the date specified above in **DATES** to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Phadrea Ponds, NPS Information Collection Clearance Officer (ADIR–ICCO), 13461 Sunrise Valley Drive (MS–244) Reston, VA 20192 (mail); or *phadrea_ponds@nps.gov* (email). Please include 1024–NEW (CCRP) in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this information collection request (ICR), contact Larry Perez, Communications Coordinator, NPS Climate Change Response Program at *larry_perez@nps.gov;* (email) or 970–267–2136 (phone). Please reference OMB Control Number 1024–NEW (CCRP) in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States. You may also view the ICR at *https://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501*et seq.)* and 5 CFR 1320.8(d)(1), we provide the public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on October 14, 2022 (87 FR 62442). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The National Park Service (NPS) is authorized by the National Park Service Protection, Interpretation, and Research in System (54 U.S.C. 100701) statutes to collect information used to enhance the management and planning of parks and their resources. The Climate Change Response Program (administered through the Natural Resource Stewardship and Science directorate) and the U.S. Fish and Wildlife Service (FWS) Human Dimensions Branch (administered through the Natural Resource Program Center within the National Wildlife Refuge System) are partnering to conduct a voluntary, on-site survey to understand park and refuge visitors' attitudes, perceptions, and beliefs about climate-related topics.

The National Park System and the National Wildlife Refuge System protect places, resources, and experiences of importance to the American public. But climate change has serious implications for the protection of landscapes, ecosystems, recreational opportunities, and visitor experiences in parks and refuges. Thus, the NPS and FWS seek to better understand visitors' understanding and concerns about climate change.

The NPS and FWS administer high-quality programs of interpretation and education and communication about pressing, climate-related topics is increasingly necessary. Audience analysis is important for guiding such efforts. The results of this survey will provide insight into topics, methods, and/or communications media of most interest to park and refuge visitors.

Title of Collection: Visitor Perceptions of Climate Change Study.

OMB Control Number: 1024–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: General Public.

Total Estimated Number of Annual Respondents: 28,010 (15,634 initial contacts; 363 non-response survey respondents; 12,013 on-site survey respondents).

Estimated Completion Time per Response: Varies between 1 and 7 minutes (depending on activity).

Total Estimated Number of Annual Burden Hours: 1,669 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

NPS Information Collections Clearance Officer, National Park Service.

[FR Doc. 2023–16800 Filed 8–4–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 234S180110; S2D2S SS08011000 SX064A000 23XS501520]

Notice of Intent To Prepare an Environmental Impact Statement for Signal Peak Energy, LLC's Federal Mine Plan for Federal Lease MTM–97988; Bull Mountains Mine Amendment 3 and 5 EIS

AGENCY: Office of Surface Mining Reclamation and Enforcement, Regions 5, 7–11, Interior.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) is publishing this notice to announce that it will prepare an environmental impact statement (EIS) for Signal Peak Energy, LLC's (Signal Peak) proposed Federal Mining Plan modification for Federal Lease MTM–97988 (the Project). OSMRE is preparing this EIS to address deficiencies in OSMRE's earlier analysis of environmental impacts related to a mining plan modification that the Ninth Circuit Court of Appeals identified in a 2022 decision. *350 Mont.* v. *Haaland,* 29 F.4th 1158 (9th Cir. 2022), *amended by* 50 F.4th 1254 (9th Cir. 2022). With this notice, OSMRE is also providing notification to the public that it will hold a public scoping meeting and provide for a 30-day public scoping period to receive comments on the environmental issues, alternatives, and information that OSMRE should analyze in this EIS.

DATES: OSMRE requests comments concerning the scope of the analysis in the EIS, alternatives, and identification of relevant information, studies, and analyses. All comments must be received by September 6, 2023. The public scoping meeting will be held at the Roundup Community Center in Roundup, Montana from 3:00–6:00 p.m. MDT on Wednesday, August 30, 2023.

OSMRE anticipates publishing the draft EIS in Spring 2024 and the final EIS in Fall 2024 with the Record of Decision expected to be published in early 2025.

ADDRESSES: You may submit comments related to the Project by any of the following methods:

- *Email: BULLMTNS_AMD3_EIS@icf.com* Be sure to send emails with the subject line: ATTN: Bull Mountains Mine Amd 3 EIS.
- *Mail:* ATTN: Bull Mtns Amd3 EIS, C/O: Roberta Martínez Hernández, OSMRE Western Regions 5, 7–11, P.O. Box 25065, Lakewood, CO 80225–0065.

FOR FURTHER INFORMATION CONTACT: Roberta Martínez Hernández, NEPA Project Manager; telephone (303) 236–4705; email: *rmartinezhernandez@osmre.gov* or at the address provided in the **ADDRESSES** section.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: OSMRE Regions 5 and 7 through 11 will prepare an EIS for the Bull Mountains Mine Mining Plan modification to address a 2022 Ninth Circuit Court of Appeals decision related to the 2018 mining plan modification that OSMRE prepared for Federal Coal Lease MTM 97988. *350 Mont.,* 29 F.4th 1158. Mining of Federal coal was allowed to continue during the litigation challenging OSMRE's environmental assessment under the National Environmental Policy Act (NEPA), but the mining plan modification approval was ultimately vacated by the U.S. District Court for the District of Montana on February 10, 2023, requiring Signal Peak to immediately stop mining any remaining Federal coal authorized under the vacated mining plan. *350 Mont.* v. *Haaland,* 2023 U.S. Dist. LEXIS 23219 (D. Mont. Feb. 10, 2023), *motion for clarification denied,* 2023 U.S. Dist. LEXIS 33516 (D. Mont. Feb. 28, 2023). In accordance with the Mineral Leasing Act of 1920 (MLA), the Assistant Secretary for Land and Minerals Management (ASLM) must approve, disapprove, or approve the Project with conditions because the Project contains lands with leased Federal coal associated with MTM 97988. The Bull Mountains Mine is operated by Signal Peak under Permit C1993017, issued by Montana Department of Environmental Quality (MDEQ), in accordance with its state mine permit.

OSMRE will complete a corrective NEPA analysis by preparing an EIS to analyze the potential environmental effects of the Project, including potential effects on climate from project-related greenhouse gas emissions. The EIS will analyze the potential environmental effects of mining all of the Federal coal under the originally proposed mining plan modification, including the mining that already occurred under the now-vacated ASLM approval and the mining of the remaining Federal coal. The EIS will also consider an additional amendment currently pending with MDEQ which would add 7.1 million tons (Mt) of Federal coal to the mining plan, and any new information available when analyzing potential impacts to other resources in the environment that could result if mining of the Federal coal is approved.

The Bull Mountains Mine is located approximately 30 miles north of Billings, Montana. The Project as proposed in 2015 allowed for 475 acres of additional surface disturbance and 37.5 Mt of recoverable Federal coal, extending the life of mine (LOM) by 11.5 years. Following the 2023 vacatur of the mining plan approval, mining of Federal coal at this site is currently stopped unless and until ASLM approves a new mining plan. As proposed, this mining plan modification, including the additional 7.1 Mt of Federal coal from lease MTM–97988 (Amendment 5), would allow for 249 acres of additional surface disturbance and recovery of an additional 30.6 Mt of Federal coal, extending the LOM by approximately 8 to 10 years, depending on production rates. The annual production rate used to calculate the environmental impacts resulting from the Project is approximately 8 to 10 million tons per year (Mtpy), which is below the maximum permitted production rate of 15 Mtpy set by MDEQ-Air Quality Division Air Quality Permit MAQP #3179–12. If the Bull Mountains Mine maintains an annual production rate of approximately 8 to 10 Mtpy, the Project could extend production until 2032, but this date could vary depending on annual production rates. As with other areas of the Bull Mountains Mine, coal would be primarily sold, exported, and combusted in South Korea and Japan, with approximately 4 percent being sent to domestic customers across the USA. If the Project is not approved, the Bull Mountains Mine would be expected to continue producing coal for approximately 1 to 2 years, ending in 2024 to 2025, depending on production rates. The surface of the permit area is a mix of private, State, and Federally owned land, and current surface land uses in the Project area include grazing and wildlife habitat.

Purpose and Need for the Proposed Action

On October 14, 2022, the Ninth Circuit Court of Appeals held that OSMRE failed to adequately examine the impacts of greenhouse gas emissions resulting from the 2015 Federal mining plan modification in OSMRE's 2018 Environmental Assessment and remanded the case to the U.S. District Court for the District of Montana. On February 10, 2023, the District Court

determined that vacatur of the approved Federal mining plan was necessary while OSMRE prepared the updated NEPA analysis. *350 Mont.,* 2023 U.S. Dist. Lexis 23219.

The purpose of this EIS is to complete a corrective NEPA analysis to analyze the potential environmental effects of the Project, including potential effects on climate from project-related greenhouse gas emissions. The EIS will consider any new information available in analyzing potential impacts to other resources in the environment that could result if mining of the Federal coal is approved, and will also consider the potential effects of proposed Amendment 5, which is pending before MDEQ.

In accordance with the MLA, the Department of the Interior's ASLM must approve, disapprove, or approve the Project with conditions because the Project contains lands with leased Federal coal. This EIS will assist OSMRE in preparing a recommendation to ASLM to approve, disapprove, or approve with conditions the Federal mining plan modification. Signal Peak, the current mine operator, must obtain approval from ASLM to access and recover the Federal coal reserves in Federal Coal Lease MTM 97988.

Preliminary Proposed Project and Alternatives

The Project as proposed in 2015 allowed for 475 acres of additional surface disturbance and recovery of an additional 37.5 Mt of recoverable Federal coal, extending the LOM by 11.5 years. If approved by ASLM, the proposed mining plan modification under review in this EIS would allow for an additional 249 acres of additional surface disturbance, recovery of an additional 30.6 Mt of Federal coal, and extend the LOM by approximately 8 to 10 years. Signal Peak started operation in 1991 and could continue to operate until approximately 2032 under the proposed Federal mining plan modification, depending on production rates. The EIS will evaluate the proposed action alternative, a no-action alternative, and at least one additional alternative that would result in lower greenhouse gas emissions than the proposed action.

Summary of Expected Impacts

OSMRE has completed internal scoping and identified preliminary analysis issues that will be evaluated in the EIS. Reasonably foreseeable effects of mining Federal coal will be evaluated for the following resources:

- Air Quality, including air pollutants and related values such as visibility (haze) and atmospheric deposition
- Combustion of greenhouse gases as it relates to climate change
- Surface water and groundwater quality and quantity (including impacts to wetlands)
- Socioeconomics
- Environmental Justice
- Federally listed threatened/endangered species
- Geology
- Soils
- Cultural Resources
- Visual Resources
- Wildlife
- Transportation and Electrical Transmission
- Land Use and Realty
- Topography and Physiography
- Solid and Hazardous Materials
- Human Health
- Vegetation (including noxious weeds and invasive species)
- Noise and Vibration

Anticipated Permits and Authorizations

ASLM action on the Federal mining plan modification.

Schedule for the Decision-Making Process

OSMRE anticipates signing the Record of Decision in early 2025, and that ASLM will make a decision on the Federal mining plan modification in Spring 2025.

Public Scoping Process

This notice of intent initiates the scoping process, which guides the development of the EIS. In addition to this notice and the project web page on OSMRE's website at *https://www.osmre.gov/laws-and-regulations/nepa/projects,* interested stakeholders, agencies, and Tribes will be notified of the 30-day comment period via mailed letters. All public scoping comments must be submitted by email or by hard copy mail to the addresses listed under **ADDRESSES**. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made public at any time. While you may request in your comment to withhold your personal identifying information from public review, OSMRE cannot guarantee that this will occur.

The project web page includes the description of the Project as submitted by Signal Peak, a map of the proposed mining area, and information about how to submit comments on issues or concerns related to the Project that may need to be analyzed in the EIS.

OSMRE will review public scoping comments and prepare a scoping summary report. The scoping summary report will be used by OSMRE to identify issues for further analysis, resources and issues that can be dismissed from detailed analysis because they are not present or not affected, and potential alternatives to be analyzed. The scoping summary report will be made available to the public as an appendix to the draft EIS.

Request for Identification of Potential Alternatives, Information, and Analyses Relevant to the Proposed Action

In addition to comments concerning the scope of the EIS analysis, commenters are encouraged to identify relevant information, studies, and analyses that would assist the Department in making its decision and identifying potential alternatives to the Project.

Lead and Cooperating Agencies

OSMRE is the lead agency for this EIS, and the Bureau of Land Management is a cooperating agency. MDEQ has been invited to be a cooperating agency on this EIS. Other Federal agencies, State, Tribal, and local governments with jurisdiction by law or special expertise that are interested in participating in the preparation of this EIS should contact the above mentioned NEPA Project Manager.

Decision Maker

Assistant Secretary of Land and Minerals Management.

Nature of Decision To Be Made

Informed, in part, by the EIS analysis, OSMRE will make a recommendation to ASLM about the Federal mining plan modification associated with the Federal coal tracts included in Federal Coal Lease MTM 97988. ASLM will consider OSMRE's recommendation and decide whether the mining plan modification will be approved, disapproved, or approved with conditions. OSMRE's recommendation to ASLM is based, at a minimum, on the documentation specified at 30 CFR 746.13.

David Berry,

Regional Director, Unified Regions 5, 7–11.

[FR Doc. 2023–16846 Filed 8–4–23; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1368]

Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 30, 2023, under section 337 of the Tariff Act of 1930, as amended, on behalf of JUUL Labs, Inc. of Washington, DC and VMR Products LLC of San Francisco, California. A letter supplementing the complaint was filed on July 17, 2023. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vaporizer devices, cartridges used therewith, and components thereof by reason of the infringement of certain claims of U.S. Patent No. RE49,114 (''the '114 patent''); U.S. Patent No. 10,130,123 (''the '123 patent''); U.S. Patent No. 10,709,173 (''the '173 patent''); U.S. Patent No. 11,134,722 (''the '722 patent''); and U.S. Patent No. 11,606,981 (''the '981 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2023).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on August 1, 2023, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 5–7, 29, 30, 36, 43, 44, 76, 77, 80, 81, 86, 89, and 93 of the '114 patent; claims 14, 16, 18, 27, 29, 31, and 32 of the '123 patent; claims 1–4, 6, 7, 15, 16, 18–25, 28, and 30 of the '173 patent; claims 1, 3, 5, and 7–21 of the '722 patent; and claims 1, 2, 5, 6, 8–11, and 13–18 of the '981 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''vaporizer devices (ENDS devices), cartridges used therewith (sometimes referred to as 'pods'), and components thereof (cartridge housings, atomizers, atomizer subassemblies, device subassemblies)'';

(3) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

JUUL Labs, Inc., 1000 F Street NW, Washington, DC 20004

VMR Products LLC, 560 20th Street, San Francisco, California 94107

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

NJOY, LLC, 8825 N 23rd Avenue, Suite 100, Phoenix, Arizona 85021

NJOY Holdings, Inc., 9449 N 90th Street, Suite 201, Scottsdale, Arizona 85258

Altria Group, Inc., 6601 W Broad Street, Richmond, Virginia 23230

Altria Group Distribution Company, 6601 W Broad Street, Richmond, Virginia 23230

Altria Client Services LLC, 6601 W Broad Street, Richmond, Virginia 23230

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 1, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–16774 Filed 8–4–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1304]

Certain Wet Dry Surface Cleaning Devices; Notice of a Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination (''FID'') issued by the Chief Administrative Law Judge (''CALJ''), finding a violation of section 337 as to U.S. Patent Nos. 11,076,735 (''the '735 patent'') and 11,071,428 (''the '428 patent'') and no violation of section 337 as to U.S. Patent Nos. 11,122,949 (''the '949 patent''), 10,820,769 (''the '769 patent''), and 11,096,541 (''the '541 patent''), in the above-captioned investigation. The Commission also requests written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On March 9, 2022, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by Bissell Inc. and Bissell Homecare, Inc., both of Grand Rapids, Michigan (collectively, ''Complainants''). *See* 87 FR 13311–12 (March 9, 2022). The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wet dry surface cleaning devices by reason of infringement of certain claims of the '735 patent, the '428 patent, the '949 patent, the '541 patent, and the '769 patent. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation names as respondents Tineco Intelligent Technology Co., Ltd. of Suzhou City, China; TEK (Hong Kong) Science & Technology Ltd. of Hong Kong; and Tineco Intelligent, Inc. of Seattle, Washington (collectively, ''Respondents''). *Id.* The Office of Unfair Import Investigations is not participating in this investigation.

On March 24, 2023, the CALJ issued the FID, finding that a violation of section 337 has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain wet dry surface cleaning devices that infringe asserted claims 1, 13, and 15 of the '735 patent and asserted claim 1 of the '428 patent. The FID further finds no violation of section 337 with respect to the asserted claims of the '949 patent, the '769 patent, and the '541 patent. On April 7, 2023, the CALJ issued a recommended determination (''RD'') on remedy and bonding should the Commission find a violation of section 337. Specifically, if a violation is found, the RD recommends the Commission issue a limited exclusion order directed to the infringing products and cease and desist orders directed to each of the Respondents. The RD further recommends setting a bond of $49.01 for infringing iFloor 3 products, $99.01 for infringing Floor ONE S3 products, and $0 for all other infringing accused products for any importations of infringing products during the period of Presidential review.

On April 7, 2023, Complainants filed a combined petition and contingent petition requesting review of certain findings. Specifically, Complainants seek review of the FID's non-infringement findings as to the '949, '541, and '769 patents, finding that Complainants failed to satisfy the technical prong for the '541 patent, finding that certain redesigned accused products do not infringe the '735 and '428 patents, and waiver of Complainants' infringement argument as to the '428 patent. Complainants also seek contingent review of certain economic prong findings. That same day, Respondents filed a combined petition and contingent petition requesting review of certain findings. Specifically, Respondents seek review of the FID's findings that the original accused products infringe the '735 and '428 patents, that the asserted claims of the '735 and '428 patents are not invalid, that Complainants satisfied the technical prong of the domestic industry requirement as to the '735 and '428 patents, and that Complainants satisfied the economic prong of the domestic industry requirement for all of the Asserted Patents. *See* RPet. Respondents also seek contingent review of the FID's findings that the asserted claims of the '949, '541, and '769 patents are not invalid. On April 17, 2023, Complainants and Respondents filed their respective responses to the petitions for review.

On May 8, 2023, Representative Hillary J. Scholten submitted a response to the Commission's notice seeking public interest submissions. EDIS Doc. ID 795898; *see* 88 FR 22479–80 (Apr. 13, 2023). On May 9, 2023, Complainants filed a submission on the public interest pursuant to Commission Rule 210.50(a)(4). 19 CFR 210.50(a)(4).

Having reviewed the record of the investigation, including the FID, the parties' submissions to the CALJ, the petitions for review, and the responses thereto, the Commission has determined to review the FID in part. Specifically, the Commission has determined to review: (1) the FID's infringement findings for the '949, '769, and '541 patents; (2) the FID's technical prong findings for the '541 patent; (3) the FID's invalidity findings for the '735 and '428 patents; and (4) the FID's economic prong findings. The Commission has determined not to review any other findings presented in the FID.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC

Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and a cease and desist order would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the CALJ on remedy and bonding.

In their initial submission, Complainants are also requested to identify the remedy sought and Complainants are requested to submit proposed remedial orders for the Commission's consideration. Complainants are further requested to state the dates that the Asserted Patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on August 15, 2023. Reply submissions must be filed no later than the close of business on August 22, 2023. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Opening submissions are limited to 20 pages. Reply submissions are limited to 10 pages.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1304) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on August 1, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 1, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–16741 Filed 8–4–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1323]

Certain Video Processing Devices and Products Containing the Same; Notice of Commission Decision To Review and, on Review, To Affirm With Modifications an Initial Determination Granting Summary Determination of Invalidity as to U.S. Patent 8,139,878 and to Take No Position as to U.S. Patent 7,769,238; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review an initial determination (''ID'') (Order No. 47) of the presiding Administrative Law Judge (''ALJ'') granting summary determination of invalidity based on obviousness-type double patenting. On review, the Commission affirms with modifications the ID's finding that the asserted claims of U.S. Patent No. 8,139,878 (''the '878 patent'') are invalid. The Commission takes no position as to the ID's findings with respect to the '238 patent, except to the extent those findings also support the ID's invalidity findings with respect to the '878 patent. Accordingly, the Commission terminates the investigation with a finding of no violation of section 337 of the Tariff Act of 1930, as amended (''section 337''). The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission

may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On August 8, 2022, the Commission instituted this investigation under section 337 based on a complaint filed by VideoLabs, Inc. of Palo Alto, California (''Complainant'' or ''VideoLabs''). *See* 87 FR 48198–99 (Aug. 8, 2022). The complaint, as supplemented, alleged a violation of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain video processing devices and products containing the same by reason of infringement of certain claims of U.S. Patents Nos. 7,769,238 (''the '238 patent''); 8,139,878 (''the '878 patent''); 7,372,452 (''the '452 patent''); and 8,208,542 (''the '542 patent''). *See id.* The complaint also alleged the existence of a domestic industry. *See id.* The notice of investigation named as respondents: (1) Acer Inc. of New Taipei City, Taiwan, and Acer America Corporation of San Jose, California (collectively, ''Acer''); (2) ASUSTeK Computer Inc. of Taipei, Taiwan, and ASUS Computer International of Fremont, California (collectively, ''ASUS''); (3) Motorola Mobility LLC of Chicago, Illinois, Lenovo Group Limited of Quarry Bay, Hong Kong S.A.R. of China, and Lenovo (United States) Inc. of Morrisville, North Carolina (collectively, ''Lenovo''); and (4) Micro-Star International Co., Ltd. of New Taipei City, Taiwan, and MSI Computer Corp. of City of Industry, California (collectively, ''MSI''). *See id.* The Office of Unfair Import Investigations (''OUII'') is also named as a party in this investigation. *See id.*

Subsequently, the investigation was terminated in part as to the Acer respondents based on settlement. *See* Order No. 18 (Oct. 24, 2022), *unreviewed by* Comm'n Notice (Nov. 10, 2023). Likewise, the investigation was terminated in part as to the Lenovo respondents based on settlement. *See* Order No. 37 (Jan. 27, 2023), *unreviewed by* Comm'n Notice (Feb. 28, 2023). Furthermore, the investigation was terminated in part as to the MSI respondents based on settlement. *See* Order No. 38 (Feb. 7, 2023), *unreviewed by* Comm'n Notice (Mar. 7, 2023). The ASUS respondents remain in the investigation.

The Commission terminated the '452 and '542 patents based on the withdrawal of the complaint as to those patents. *See* Order No. 13 (Sept. 7, 2022), *unreviewed by* Comm'n Notice (Sept. 26, 2022); Order No. 40 (Feb. 15, 2023), *unreviewed by* Comm'n Notice (Mar. 22, 2023). Claim 1 of the '238 patent and claims 1–4 of the '878 patent remain asserted in this investigation.

On March 22, 2023, the ASUS respondents filed a corrected motion for summary determination of invalidity based on obviousness-type double patenting. On April 3, 2023, Complainant and OUII filed responses in opposition to the motion.

On May 1, 2023, the ALJ issued the subject ID (Order No. 47) granting the motion for summary determination that the asserted claims are invalid based on obviousness-type double patenting, thereby terminating the investigation in its entirety.

On May 11, 2023, Complainant filed a petition for Commission review of the subject ID. On May 18, 2023, the ASUS respondents and OUII filed responses to the petition. On May 23, 2023, Complainant filed a motion for leave to file a reply in support of its petition. On May 26 and 31, respectively, the ASUS respondents and OUII filed responses in opposition to Complainant's motion for leave to file a reply.

On July 10, 2023, Complainant filed a motion to terminate the investigation as to the '238 patent and a motion to supplement the record. On July 13, 2023, the ASUS respondents filed a response to Complainant's motion to supplement the record. No other responses were filed.

Having examined the record of this investigation, including the ID and the parties' submissions, the Commission has determined to review, and on review, to affirm the subject ID with modifications with respect to the '878 patent and to take no position with respect to the '238 patent. More specifically, as explained in the Commission Opinion issued concurrently herewith, the Commission has determined to affirm with modifications the ID's finding that the asserted claims of the '878 patent are invalid based on obviousness-type double patenting. The Commission takes no position as to the ID's findings with respect to the '238 patent, except to the extent those findings also support the ID's invalidity findings with respect to the '878 patent. The Commission adopts all findings in the ID that are not inconsistent with the Commission's determination. The Commission has also determined to grant Complainant's motion for leave to file a reply solely to the extent that the reply addresses the ASUS respondents' and OUII's positions that Complainant has waived certain arguments made in its petition for review. The Commission has further determined to grant Complainant's motion to terminate the investigation as to the '238 patent and Complainant's motion to supplement the record.

Accordingly, the Commission terminates the investigation with a finding of no violation of section 337. The investigation is terminated.

The Commission's vote for this determination took place on August 1, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 1, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–16773 Filed 8–4–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–407]

RIN 1117–AB40 and 1117–AB78

Practice of Telemedicine: Listening Sessions

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of meeting.

SUMMARY: The Drug Enforcement Administration (DEA) is conducting public listening sessions to receive additional input concerning the practice of telemedicine with regards to controlled substances and potential safeguards that could effectively prevent and detect diversion of controlled substances prescribed via telemedicine. Specifically, DEA is inviting all interested persons, including medical practitioners, patients, pharmacy professionals, industry members, law enforcement, and other third parties to express their views at the listening sessions concerning the advisability of permitting telemedicine prescribing of certain controlled substances without any in-person medical evaluation at all, the availability and types of data that would be useful in detecting diversion of controlled substances via telemedicine that are either already reported or could be reported, and specific additional safeguards that could be placed around the prescribing of

schedule II controlled substances via telemedicine.

DATES: The listening sessions will be held on Tuesday, September 12, 2023, and Wednesday, September 13, 2023, from 9 a.m. to 5:30 p.m. at DEA Headquarters, 700 Army Navy Drive, Arlington, VA 22202; (202) 307–1000. Check-in will begin at 8 a.m.

Meeting Attendance: Persons wishing to attend the listening sessions in person, space permitting, must complete and submit the attendance form available at DEA's Diversion Control Division website, *https://apps.deadiversion.usdoj.gov/ListeningSession,* no later than August 21, 2023. There is no fee to submit the attendance form or to attend the listening sessions. In-person attendance requests will be granted via random lottery among those who have submitted timely attendance forms. The listening sessions will also be livestreamed online.

Meeting Presentations: DEA is accepting requests to make limited oral presentations during the listening sessions, as discussed further in this document. Oral presentations may be given in-person or by video teleconference. Persons wishing to give an oral presentation at the listening sessions, space and time permitting, must complete and submit the attendance form available at DEA's Diversion Control Division website *https://apps.deadiversion.usdoj.gov/ListeningSession,* check the box indicating the desire to present at the listening sessions, and provide a summary of the presentation in the appropriate form field. This form must be submitted no later than August 21, 2023. Persons and groups having similar interests may wish to consider consolidating their information for an oral presentation through a single representative. After reviewing the requests to present, DEA will respond to all persons who request to provide an oral presentation to notify them of the status of their request. DEA will exercise its discretion to select a cross-section of persons and organizations to present at the listening sessions based on: (1) the person or organization's ability to respond to the specific questions presented below with new information, including the capacity to provide data responsive to the questions; and (2) the person or organization's ability to represent stakeholders on a given issue, position, or interest as raised by the requests. If selected to give an oral presentation, DEA will notify the presenting person or organization of the amount of time available to present and the approximate time the participant's presentation is scheduled to begin.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Background

Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act), a prescribing practitioner—subject to certain exceptions—may prescribe controlled substances to a patient only if the practitioner has, at some point previously, conducted an in-person evaluation of that patient.

The Ryan Haight Act and DEA's implementing regulations do not limit a practitioner's ability to prescribe controlled substances for a patient after the practitioner has conducted at least one in-person medical evaluation of the patient. The Ryan Haight Act applies only where the prescribing practitioner wishes to prescribe controlled substances and has not conducted an in-person medical evaluation prior to the issuance of the prescription. In addition, the Ryan Haight Act and DEA's implementing regulations do not apply to telemedicine, telehealth, or telepsychiatry not involving the issuing of prescriptions for controlled substances or to other aspects of telemedicine, telehealth, or telepsychiatry that are not otherwise specified in the Controlled Substances Act (CSA).

In response to the COVID–19 Public Health Emergency (COVID–19 PHE) as declared by the Secretary of the Department of Health and Human Services (HHS) on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), DEA granted temporary exceptions to the Ryan Haight Act and DEA's implementing regulations under 21 U.S.C. 802(54)(D),[1] thereby allowing the prescribing of controlled substances via telemedicine encounters—even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient—in order to prevent lapses in care.

DEA recognizes the importance of telemedicine in providing Americans with access to needed medications, and DEA has been, and remains, committed to expanding access to telemedicine in a way that puts patients—and their safety—first, is simple to understand and apply, reflects technological advancements, and is consistent with lessons learned during the COVID–19 PHE and the ongoing opioid epidemic.

Accordingly, on March 1, 2023, prior to the expiration of the COVID–19 PHE and with the intent to make permanent some of the telemedicine flexibilities established during the COVID–19 PHE, DEA, in concert with HHS, promulgated two notices of proposed rulemaking (NPRMs) in the **Federal Register**—*Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation* [2] (the ''General Telemedicine NPRM'') and *Expansion of Induction of Buprenorphine via Telemedicine Encounter* [3] (the ''Buprenorphine NPRM'').[4] These proposed rules sought to expand patient access to prescriptions for controlled substances via telemedicine encounters relative to the pre-COVID–19 PHE landscape, when consistent with public health and safety, while maintaining effective controls against diversion. More specifically, the General Telemedicine NPRM would allow for the telemedicine prescription of non-narcotic [5] schedule III–V controlled substances when certain circumstances are met, and impose an initial limit on telemedicine prescriptions for a controlled substance to a 30-day supply.[6] To prescribe an additional supply to that patient (either within that initial 30 days or after the

[1] William T. McDermott, DEA Dear Registrant letter, Drug Enforcement Administration (March 25, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf;* Thomas W. Prevoznik, DEA Dear Registrant letter, Drug Enforcement Administration (March 31, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.*

[2] 88 FR 12,875 (Mar. 1, 2023).

[3] 88 FR 12,890 (Mar. 1, 2023).

[4] The NPRMs were promulgated under authority granted to DEA and HHS pursuant to 21 U.S.C. 802(54)(G).

[5] Under the CSA, narcotic drugs are drugs that contain opiates, cocaine, or ecgonine, as well as certain related plant material. 21 U.S.C. 802(17). This definition includes buprenorphine, a narcotic drug that has been approved by the Food and Drug Administration for maintenance and detoxification treatment of opioid use disorder.

[6] The regulations proposed in the General Telemedicine NPRM would also allow a practitioner employed by the Veterans Health Administration or who has received a qualifying telemedicine referral from a practitioner who has conducted an in-person medical exam of the patient to prescribe via telemedicine any controlled substance (including schedule II controlled substances and narcotics) that the practitioner is otherwise authorized to prescribe, subject to the same circumstances and initial 30-day limit as telemedicine prescriptions for schedules III–V non-narcotic controlled substances.

completion of the initial 30-day supply), the prescribing practitioner would generally be required to evaluate the patient in person. The Buprenorphine NPRM would impose the same initial 30-day supply limit and in-person medical evaluation requirements. The comment period for the two NPRMs closed on March 31, 2023.

DEA received a total of 38,369 public comments in response to the NPRMs—35,454 comments on the General Telemedicine NPRM and 2,915 comments on the Buprenorphine NPRM. When combined, these were among the highest number of public comments received on an NPRM in DEA's history. DEA thanks all commenters for their input and has been considering the comments carefully. On May 10, 2023, DEA and HHS temporarily extended the telemedicine flexibilities in place during the COVID–19 PHE to permit further consideration of the comments and avoid lapses in care.[7]

Among the 38,369 comments submitted in response to the NPRMs, a significant majority expressed concern, with respect to at least some controlled substances, that the proposed regulations placed limitations on the supply of controlled substances that could be prescribed via telemedicine prior to an in-person medical evaluation. In addition, several hundred comments specifically raised the possibility of a separate Special Registration for those practitioners who seek to prescribe controlled substances without conducting an in-person medical evaluation of patients at all.

DEA is open to considering—for some controlled substances—implementation of a separate Special Registration for telemedicine prescribing for patients without requiring the patient to ever have had an in-person medical evaluation at all. DEA also observes that making permanent some telemedicine flexibilities on a routine and large-scale basis would potentially create a new framework for medicine that fundamentally expands access to controlled substances in a way that warrants a new framework for accountability based, in part, on increased data collection and visibility into prescription practices in order to ensure patient safety and prevent diversion in near-real-time.[8]

Accordingly, DEA has decided to hold the aforementioned public listening sessions to gather new information from interested persons. While DEA welcomes all relevant information or opinions regarding telemedicine, DEA is particularly interested in the following questions:

- If telemedicine prescribing of schedule III–V medications were permitted in the absence of an in-person medical evaluation, what framework, including safeguards and data, with respect to telemedicine prescribing of schedule III–V medications do you recommend to help DEA ensure patient safety and prevent diversion of controlled substances?
- Should telemedicine prescribing of schedule II medications never be permitted in the absence of an in-person medical evaluation? Are there any circumstances in which telemedicine prescribing of schedule II medications should be permitted in the absence of an in-person medical evaluation? If it were permitted, what safeguards with respect to telemedicine prescribing of schedule II medications specifically would you recommend to help DEA ensure patient safety and prevent diversion of controlled substances?
- If *practitioners* are required to collect, maintain, and/or report telemedicine prescription data to DEA, what pieces of data should be included or excluded? What data is already reported to federal and state authorities, insurance companies, and other third parties?
- If *pharmacies* are required to collect, maintain, and/or report telemedicine prescription data to DEA, what pieces of data should be included or excluded? What data is already reported to federal and state authorities, insurance companies, and other third parties?

Meeting Participation

These listening sessions are open to the public. DEA registrants (*i.e.,* practitioners, pharmacies, manufacturers, distributors, and reverse distributors), ultimate users of controlled substances (*i.e.,* patients and members of their households), persons and organizations representing state and local governments, law enforcement agencies, long term care facilities (*i.e.,* hospices, nursing homes, and in-home care groups), and other concerned organizations may be particularly interested in these listening sessions.

Persons wishing to attend in person or provide a limited oral presentation must register on the Diversion Control Division website at *https://apps.deadiversion.usdoj.gov/ListeningSession,* as outlined above. These listening sessions will also be livestreamed. DEA will publicize instructions for accessing the livestream at a later date. A copy of the transcript from the listening sessions will be made available at the DEA Diversion Control Program website, *https://www.deadiversion.usdoj.gov.* That transcript will be considered part of the rulemaking record.

Persons needing any accommodations for a disability (*e.g.,* sign language interpreter) are asked to notify DEA with their accommodation request no later than August 21, 2023. Such notification should be made to Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

As these listening sessions are open to the public, confidential business information or other proprietary information should NOT be shared.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 2, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal

[7] On May 10, 2023, DEA and HHS jointly promulgated a temporary final rule (Temporary Rule) that extended the telemedicine flexibilities in place during the COVID–19 PHE to avoid lapses in care given the then-pending May 11, 2023 expiration of the COVID–PHE. The Temporary Rule extends the full set of telemedicine flexibilities regarding prescription of controlled substances that were in place during the COVID–19 PHE through November 11, 2023. In addition, for any practitioner-patient relationships that have been or will be established on or before November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled substances in place during the COVID–19 PHE will continue to be permitted via a one-year grace period through November 11, 2024. In other words, if a patient and a practitioner have established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that have governed the relationship to that point are permitted until November 11, 2024. *Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications,* 88 FR 30037 (May 10, 2023) (to be codified at 21 CFR 1307 and 42 CFR 12).

[8] Under the Ryan Haight Act, as a general matter, prescriptions for controlled substances may not be issued without a prior in-person medical evaluation of a patient. *See* 21 U.S.C. 829(e)(1), 2(A)(i). This reflects a background presumption that, when an in-person touchpoint has not occurred, it may be more likely that there has not been ''adequate medical oversight'' underlying the issuance of a prescription for a controlled substance. *See* H.R. Rep. No. 110–869, pt. 1, at 12 (describing the general performance goals and objectives of the Ryan Haight Act as ''counter[ing] the growing sale of controlled substances over the internet without adequate medical oversight''). Notwithstanding the Ryan Haight Act's general prohibition, the law's provisions also created an exception to the prior in-person medical evaluation requirement for practitioners who engage in the practice of telemedicine under a special registration framework. *See* 21 U.S.C. 829(e)(3)(A), 831(h).

Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–16889 Filed 8–4–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Worker's Compensation Programs

[OMB Control No. 1240–0015]

Proposed Extension of Information Collection; Claim for Continuance of Compensation, CA–12

AGENCY: Division of Federal Employees' Longshore and Harbor Workers' Compensation, Office of Workers' Compensation (OWCP/DFELHWC), Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance request for comment to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This request helps to ensure that: requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents can be properly assessed. Currently, OWCP/DFELHWC is soliciting comments on the information collection for Claim for Continuance of Compensation, CA–12.

DATES: All comments must be received on or before October 6, 2023.

ADDRESSES: You may submit comment as follows. Please note that late, untimely filed comments will not be considered.

Written/Paper Submissions: Submit written/paper submissions in the following way:

- *Mail/Hand Delivery:* Mail or visit DOL–OWCP/DFELHWC, Office of Workers' Compensation Programs, Division of Federal Employees' Longshore and Harbor Workers' Compensation, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210.
- OWCP/DFELHWC will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs, Office of Workers' Compensation Programs, Division of Federal Employees Longshore, and Harbor Workers' Compensation, OWCP/DFELHWC, at *suggs.anjanette@dol.gov* (email) (202) 354–9660 (voice).

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Workers' Compensation Programs administers the Federal Employees' Compensation Act, which provides for continuation of pay or compensation for work related injuries or disease that resulted from Federal employment. Under 5 U.S.C. 8133 of the Act, eligible survivors of deceased employees receive compensation benefits on account of the employee's death. OWCP has to monitor death benefits for current marital status, potential for dual benefits, and other criteria for qualifying as a beneficiary under the law. Under 5 U.S.C. 8149, the Secretary of Labor may prescribe rules and regulations necessary for the administration and enforcement of this subchapter. Under CFR 10.414, the CA–12 is sent annually to beneficiaries in death cases to verify that their marital and/or beneficiary status has not changed to remain entitled to benefits.

II. Desired Focus of Comments

OWCP is soliciting comments concerning the proposed collection related to the Claim for Continuance of Compensation, CA–12. OWCP is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of OWCP/DFELHWC's estimate of the burden related to the information collection, including the validity of the methodology and assumptions used in the estimate;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the information collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Background documents related to this information collection request are available at *https://regulations.gov* and at DOL–OWCP/DFELHWC located at 200 Constitution Avenue NW, Room S–3323, Washington, DC 20210. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This information collection requests concerns the Claim for Continuance of Compensation, CA–12. OWCP/DFELHWC has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request from the previous information collection request.

Type of Review: Extension, without change, or a currently approved collection.

Agency: Office of Workers' Compensation Programs, Division of Federal Employees' Longshore, and Harbor Workers' Compensation, OWCP/DFELHWC.

Title of Collection: Claim for Continuance of Compensation.

OMB Number: 1240–0015.

Affected Public: Individuals or households.

Number of Respondents: 2,894.

Frequency: Annually.

Estimated Annualized Burden Hours and Cost Table: $6,895.00.

Number of Responses: 2,894.

Annual Burden Hours: 241.

Total Respondent or Recordkeeper Cost: $1,483.00.

OWCP Form: Form CA–12, Claim for Continuance of Compensation.

Comments submitted in response to this notice will be summarized in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and will be available at *https://www.reginfo.gov.*

Anjanette Suggs,

Certifying Officer.

[FR Doc. 2023–16711 Filed 8–4–23; 8:45 am]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Office of the Worker's Compensation Programs

[OMB Control No. 1240–0009]

Proposed Extension of Information Collection; Notice of Recurrence (CA–2a)

AGENCY: Division of Federal Employees' Longshore and Harbor Workers' Compensation, Office of Workers' Compensation (OWCP/DFELHWC), Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance request for comment to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This request helps to ensure that: requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents can be properly assessed. Currently, OWCP/DFELHWC is soliciting comments on the information collection for Notice of Recurrence, CA–2a.

DATES: All comments must be received on or before October 6, 2023.

ADDRESSES: You may submit comment as follows. Please note that late, untimely filed comments will not be considered.

Written/Paper Submissions: Submit written/paper submissions in the following way:

- *Mail/Hand Delivery:* Mail or visit DOL–OWCP/DFELHWC, Office of Workers' Compensation Programs, Division of Federal Employees' Longshore and Harbor Workers' Compensation, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210.
- OWCP/DFELHWC will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs, Office of Workers' Compensation Programs, Division of Federal Employees Longshore, and Harbor Workers' Compensation, OWCP/DFELHWC, at *suggs.anjanette@dol.gov* (email); (202) 354–9660.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Workers' Compensation Programs administers the Federal Employees' Compensation Act, (5 U.S.C. 8101, *et seq.*), which provides for continuation of pay or compensation for work related injuries or disease that result from Federal Employment. Regulation 20 CFR 10.104 designates form CA–2a as the form to be used to request information from claimants with previously accepted injuries who claim a recurrence of disability, and from their employer, if applicable. The form requests information relating to the specific circumstances leading up to the recurrence as well as information about their employment and earnings.

II. Desired Focus of Comments

OWCP is soliciting comments concerning the proposed information collection (ICR) titled, '' Notice of Recurrence'', CA–2a. OWCP/DFELHWC is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of OWCP/DFELHWC's estimate of the burden related to the information collection, including the validity of the methodology and assumptions used in the estimate;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the information collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Background documents related to this information collection request are available at *https://regulations.gov* and at DOL–OWCP/DFELHWC located at 200 Constitution Avenue NW, Room S–3323, Washington, DC 20210. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This information collection request concerns Notice of Recurrence, CA–2a. OWCP/DFELHWC has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request from the previous information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Office of Workers' Compensation Programs, Division of Federal Employees' Longshore, and Harbor Workers' Compensation, OWCP/DFELHWC.

OMB Number: 1240–0009.

Affected Public: Individuals or households.

Number of Respondents: 149.

Frequency: On occasion.

Number of Responses: 149.

Annual Burden Hours: 75 hours.

Annual Respondent or Recordkeeper Cost: $60.00.

OWCP Form: CA–2a, Notice of Recurrence.

Comments submitted in response to this notice will be summarized in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and will be available at *https://www.reginfo.gov.*

Anjanette Suggs,

Certifying Officer.

[FR Doc. 2023–16713 Filed 8–4–23; 8:45 am]

BILLING CODE 4510–CH–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 21 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference or videoconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate.

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from David Travis, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *travisd@arts.gov,* or call 202–682–5001.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the

purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chair of March 11, 2022, these sessions will be closed to the public pursuant to 5 U.S.C. 10.

The upcoming meetings are:

Smart Growth America Leadership Award (review of applications): This meeting will be closed.

Date and time: September 13, 2023; 12 p.m. to 2 p.m.

Literature Fellowships: Creative Writing (review of applications): This meeting will be closed.

Date and time: September 13, 2023; 1 p.m. to 3 p.m.

Dated: August 2, 2023.

David Travis,

Specialist, National Endowment for the Arts.

[FR Doc. 2023–16789 Filed 8–4–23; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Request for Public Comment on Common Disclosure Forms for the Biographical Sketch and Current and Pending (Other) Support for Use in Submission of Research Applications

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF), on behalf of the National Science and Technology Council's (NSTC) Research Security Subcommittee, has submitted the following information collection to OMB for review and clearance in accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995. This is the second notice for public comment; the first was published in the **Federal Register** on August 31, 2022, and 100 discrete comments were received. Commenters included individuals, professional societies, institutions of high education, and Federal agencies. All comments have been considered in the development of the proposed version. A summary of the responses to the comments received, including the significant changes and clarifications to the common forms has been incorporated into the Comment Table. Please see *http://www.nsf.gov/bfa/dias/policy/.* NSF is forwarding the proposed Biographical Sketch and Current and Pending (Other) Support sections of a research application as common disclosure forms to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at: *http://www.reginfo.gov/public/do/PRAMain.* The National Science Foundation has agreed to serve as steward for collection and resolution of public comments, as well as for posting and maintaining these common disclosure forms (including subsequent revisions), as well as other associated documents. The NSTC Research Security Subcommittee, has developed this information collection as common disclosure forms to permit Federal research funding agencies beyond NSF to streamline the information collection process in coordination with OMB.

DATES: Written comments for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAmain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

ADDRESSES: Please address comments to Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite E7400, Alexandria, Virginia 22314; telephone (703) 292–7556; or send an email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

FOR FURTHER INFORMATION CONTACT: For information on the proposed common disclosure forms, contact Jean Feldman, Head, Policy Office, Division of Institution & Support, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, email: *jfeldman@nsf.gov;* telephone (703) 292–8243; FAX: (703) 292–9171.

For further information on the NSTC Research Security Subcommittee, contact Dr. Cole Donovan, Assistant Director for Research Security and Infrastructure, Office of Science and Technology Policy, Executive Office of the President, 725 17th Street NW, Washington, DC 20503; email: *ResearchSecurity@ostp.eop.gov,* telephone 202–881–4675; FAX 202–456–6027.

Comments: Comments regarding any fatal flaws in the proposed common disclosure forms should be addressed to the points of contact in the **FOR FURTHER INFORMATION CONTACT** section.

SUPPLEMENTARY INFORMATION: As required by 5 CFR 1320.8(d), comments on the information collection activities were solicited through the publication of a 60-day notice in the **Federal Register** at 87 FR 53505. NSF received 100 discrete comments in response to the 60-day notice. Commenters included individuals, professional societies, institutions of high education, and Federal agencies.

NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number, and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Title of Collection: Request for Comment regarding Common Disclosure Forms for the Biographical Sketch and Current and Pending (Other) Support.

OMB Approval Number: 3145–NEW.

Type of Request: Intent to seek approval to establish an information collection for common disclosure forms for the Biographical Sketch and Current and Pending (Other) Support for three years.

I. Background

Section 4(b) of NSPM–33 directs that ''research funding agencies shall require the disclosure of information related to potential conflicts of interest and commitment from participants in the federally funded R&D enterprise . . . The appropriate disclosure requirement varies depending on the individual's role in the United States R&D enterprise.'' Section 4(b)(vi) directs that ''agencies should standardize forms for initial disclosures as well as annual updates, . . . and should provide clear instructions to accompany these forms and to minimize any associated administrative burden.''

The NSTC Research Security Subcommittee has worked to develop consistent disclosure requirements from senior personnel, as well as to develop proposed common disclosure forms for the Biographical Sketch and Current and Pending (Other) Support sections of an application for Federal research and development (R&D) grants or cooperative agreements. The purpose of the Biographical Sketch is to assess how well qualified the individual, team, or organization is to conduct the proposed activities. The purpose of Current and Pending (Other) Support is to assess the capacity of the individual to carry out

the research as proposed and to help identify any potential scientific and budgetary overlap/duplication, as well as overcommitment with the project being proposed.

These common forms are intended to clarify what is expected of senior personnel applying for R&D funding from Federal research funding agencies. Variations among research agencies will be limited to cases: (a) where required by statute or regulation; (b) where more stringent protections are necessary for protection of R&D that is classified, export-controlled, or otherwise legally protected; or (c) for other compelling reasons consistent with individual agency authorities and as coordinated through the NSTC.

As stated in the NSPM–33 Implementation Guidance, ''the goal of these common forms and accompanying instructions is to ensure that applying for awards from any Federal research funding agency will require disclosing the same information in the same manner, to increase clarity and reduce administrative burden on the research community. In some cases, Federal research funding agencies may adapt the forms and instructions, where required by their legal authorities. Such common disclosure forms also will allow the research community to identify and point out where greater clarity may be needed.''

Agencies may develop agency- or program-specific data elements and instructions, if necessary, to meet programmatic requirements, although agencies will be instructed to minimize the degree to which they supplement the common forms. Modification, supplementation, or deviation from these common disclosure forms will require clearance by OMB/OIRA under the PRA process.

These common disclosure forms are intended to replace existing forms/formats currently used by agencies for these sections of applications, thereby increasing the consistency of disclosure forms and reducing administrative burden.

II. Invitation to Comment

The following documents are available for review and comment on the NSF website (see *https://www.nsf.gov/bfa/dias/policy/nstc_disclosure.jsp*):

a. A common Biographical Sketch form comprised of data elements and associated instructions; and

b. A common Current and Pending (Other) Support form comprised of data elements and associated instructions.

Input is welcome on any fatal flaws associated with the proposed common disclosure forms, including the accompanying instructions.

BURDEN ON THE PUBLIC

Form name	Number of proposals (estimated)	Number of respondents (estimated)	Burden time per respondent (hours)	Total
Biographical Sketch	46,500	4	2	372,000
Current and Pending (Other) Support	46,500	4	2	372,000
Total burden hours				744,000

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2023–16765 Filed 8–4–23; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

President's Committee on the National Medal of Science; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: President's Committee on the National Medal of Science (#1182).

Date and Time: October 31, 2023; 8:30 a.m.–5:00 p.m. (Eastern).

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual).

Type of Meeting: Closed.

Contact Persons: Pugh Lev, Gayle, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703.292.8580.

Purpose of Meeting: Virtual meeting to provide advice and recommendations to the President in the selection of the 2023 National Medal of Science laureates. The committee assists the President in carrying out his responsibilities under 42 U.S.C. 1880–1881.

Agenda: To review and evaluate nominations as part of the selection process for the NMS-National Medal of Science program.

Reason for Closing: The nominations being reviewed include information of a personal nature where disclosure would constitute unwarranted invasions of personal privacy. These matters are exempt under 5 U.S.C. 552b(c), (6) of the Government in the Sunshine Act.

Dated: August 1, 2023.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2023–16740 Filed 8–4–23; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–425; NRC–2023–0092]

Southern Nuclear Operating Company; Vogtle Electric Generating Plant, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to a request dated June 30, 2022, as supplemented by letters dated September 13, 2022, and January 20, and May 5, 2023, from Southern Nuclear Operating Company to allow the use of AXIOM fuel rod cladding material in lead test assemblies 7ST1, 7ST2, 7ST3, and 7ST4, for up to two cycles of operation at Vogtle Electric Generating Plant, Unit 2.

DATES: The exemption was issued on August 1, 2023.

ADDRESSES: Please refer to Docket ID NRC–2023–0092 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0092. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed

in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: John G. Lamb, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3100; email: *John.Lamb@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: August 2, 2023.

For the Nuclear Regulatory Commission.

John G. Lamb,

Senior Project Manager, Licensing Plant Branch 2–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption from 10 CFR part 50, Appendix K, for Vogtle, Unit 2, to Allow the Use of AXIOM Fuel Rod Cladding Material in Lead Test Assemblies.

NUCLEAR REGULATORY COMMISSION

Docket No. 50–425

Southern Nuclear Operating Company

Vogtle Electric Generating Plant, Unit 2

Exemption

I. Background

Southern Nuclear Operating Company (SNC, the licensee) is the holder of Facility Operating License No. NPF–81, for the Vogtle Electric Generating Plant (Vogtle), Unit 2. The license provides, among other things, that the license is subject to all rules, regulations, and orders of the Commission now or hereafter in effect.

The Vogtle, Unit 2, consists of a pressurized-water reactor located at the licensee's site in Burke County, Georgia.

II. Request/Action

By letter dated June 30, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22181B156), as supplemented by letters dated September 13, 2022 (ML22256A198), January 20, 2023 (ML23020A148), and May 5, 2023 (ML23125A269), SNC requested an exemption to title 10 of the *Code of Federal Regulations* (10 CFR), part 50, appendix K, ''ECCS [Emergency Core Cooling Systems] Evaluation Models,'' for Vogtle, Unit 2.

Specifically, SNC requested an exemption from 10 CFR part 50, appendix K to allow the use of AXIOM fuel rod cladding material in lead test assemblies (LTAs) 7ST1, 7ST2, 7ST3, and 7ST4 for up to two cycles of operation at Vogtle, Unit 2.

The regulation at 10 CFR 50.46(a)(1)(ii) provides that, ''[a]lternatively, an ECCS evaluation model may be developed in conformance with the required and acceptable features of Appendix K ECCS Evaluation Models.'' Appendix K of 10 CFR part 50 requires, in paragraph I.A.5, that ''[t]he rate of energy release, hydrogen generation, and cladding oxidation from the metal/water reaction shall be calculated using the Baker-Just equation (Baker, L., Just, L.C., 'Studies of Metal Water Reactions at High Temperatures, III. Experimental and Theoretical Studies of the Zirconium Water Reaction,' ANL–6548, page 7, May 1962).'' The regulations make no provisions for use of fuel rods clad in a material other than zircaloy or ZIRLO. Since the Baker-Just equation presumes the use of zircaloy or ZIRLO clad fuel, strict application of this provision of the rule would not permit use of the equation for AXIOM cladding for determining acceptable fuel performance.

III. Discussion

Pursuant to 10 CFR 50.12, the NRC may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, including 10 CFR part 50, appendix K when: (1) the exemptions are authorized by law, will not present an undue risk to the public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. Under 10 CFR 50.12(a)(2), special circumstances include, among other things, when application of the specific regulation in the particular circumstances would not serve, or is not necessary to achieve, the underlying purpose of the rule.

A. The Exemption is Authorized by Law

In accordance with 10 CFR 50.12, the NRC may grant an exemption from the requirements of 10 CFR part 50 if the exemption is authorized by law. The exemption requested in this instance is authorized by law, because no other prohibition of law exists to preclude the activities which would be authorized by the exemption.

This exemption would allow the licensee to insert four LTAs containing AXIOM fuel rod cladding that is neither Zircaloy nor ZIRLO, which are the cladding materials contemplated by 10 CFR 50.46(a)(1)(i). Selection of a specific cladding material in 10 CFR 50, appendix K was at the discretion of the Commission consistent with its statutory authority. No statute required the NRC to adopt this specification. As stated above, 10 CFR 50.12 allows the Commission to grant exemptions from the requirements of 10 CFR part 50. The NRC staff has determined that granting of an exemption from 10 CFR part 50, appendix K related to AXIOM fuel rod cladding, which is neither Zircaloy nor ZIRLO, will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

B. The Exemption Presents No Undue Risk to Public Health and Safety

SNC stated the following in its letter dated June 30, 2022:

The Vogtle reactors each contain 193 fuel assemblies. Each assembly consists of a matrix of 264 Zircaloy, ZIRLO®[TM], or Optimized ZIRLO®[TM] clad fuel rods with an initial composition of natural or slightly enriched uranium dioxide (UO2) as fuel material, not to exceed 5 wt% [weight-percent] enrichment. The proposed change is to load four LTAs with advanced ATF [accident tolerant fuel] features, including ADOPT fuel [2], AXIOM cladding [3], chromium coating, and four rods per LTA with up to 6 wt% enrichment, in limiting core locations for up to two cycles of operation.

This exemption will not present an undue risk to public health and safety. Reload evaluations ensure that acceptance criteria are met for the insertion of LTAs with fuel rods clad with AXIOM material. Due to similarities in the composition of the AXIOM alloy and the Optimized ZIRLO and standard ZIRLO alloys, fuel assemblies using AXIOM fuel rod cladding are evaluated using plant-specific models to address the changes in the cladding material properties. The LOCA [loss-of-coolant accident] safety analyses for VEGP [Vogtle Electric Generating Plant] are supported by the applicable site-specific Technical Specifications (TS). Reload cores are required to be operated in accordance with the operating limits specified in the TS. Thus, the granting of this exemption request will not pose an undue risk to public health and safety.

Based upon the limited number of AXIOM clad fuel rods, the safeguards in place which would detect anomalous behavior, the use of NRC-approved models to ensure that all design criteria remain satisfied, and the requirement to operate the Vogtle, Unit 2, core within TS limits, the NRC staff finds the four LTAs acceptable for Vogtle, Unit 2. In conclusion, the NRC staff finds that the requested exemption does not result in any undue risk to the public health and safety, because (1) the NRC staff has determined that the use of AXIOM cladding in this application is acceptable because there is no expected loss of safety margin associated with the use of AXIOM cladding in the pertinent limiting core locations,[1] (2) the

[1] As stated in the May 5, 2023, supplement, the LTAs will not be placed in core regions that have been shown to be limiting with respect to the control rod ejection analysis.

NRC staff has determined that SNC's evaluation of coated cladding emissivity and its effect on loss-of-coolant accident peak clad temperature (PCT) is acceptable, because data was provided demonstrating no significant difference in PCT, (3) the NRC staff has determined that SNC's evaluation of ADOPT fuel pellets in the LTAs is acceptable, because there will be no reduction in fuel performance and the applicable limitations and conditions have been implicitly addressed, and (4) the number of rods with enrichments exceeding five weight-percent Uranium 235 is small compared to the total number of fuel rods. See the NRC safety evaluation (ML23093A028) for further details.

C. The Exemption Is Consistent With the Common Defense and Security

The proposed exemption would allow the use of four LTAs with a variant cladding material. This change to the plant core configuration has no impact on security issues. Special nuclear material in the LTAs will continue to be handled and controlled in accordance with applicable regulations. Therefore, the common defense and security is not impacted by this exemption.

D. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR part 50, Appendix K, Section I.A.5 is to establish acceptance criteria for ECCS performance. In the safety evaluation (SE) contained in ML23093A028 for the license amendment request, the NRC staff evaluated for Vogtle, Unit 2, four LTAs that demonstrated the acceptability of the AXIOM cladding under LOCA conditions. The unique features of the LTAs were evaluated for effects on the LOCA analyses. The results showed that the LTAs would not adversely affect ECCS performance. Since the Baker-Just equation presumes the use of zircaloy or ZIRLO clad fuel, strict application of this provision of the rule would not permit use of the equation for AXIOM cladding for determining acceptable fuel performance. Therefore, the NRC staff concludes that application of the cladding material applicability requirements of the Baker-Just equation of 10 CFR part 50, Appendix K in this particular circumstance is not necessary for the licensee to achieve the underlying purpose of the rule.

E. Environmental Considerations

With respect to its impact on the quality of the human environment, the NRC has determined that the issuance of the exemption discussed herein meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). The NRC staff's determination that all of the criteria for this categorical exclusion are met is as follows:

The regulation 10 CFR 51.22(c)(9) states:

Issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter that changes a requirement or issuance of an exemption from a requirement, with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter; or the issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter that changes an inspection or a surveillance requirement; provided that: (i) The amendment or exemption involves no significant hazards consideration; (ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and (iii). There is no significant increase in individual or cumulative occupational radiation exposure.

Staff Analysis: The exemption is from requirements with respect to the installation or use of facility components located within the restricted area as defined in 10 CFR part 20. The criteria for determining whether an action involves a significant hazards consideration are found in 10 CFR 50.92. The proposed action involves installed four LTAs. As stated in the evaluation in ML23093A028, the Commission has previously issued a proposed finding that the amendments involve no significant hazards consideration, published in the **Federal Register** on November 8, 2022 (87 FR 67508), and there has been no public comment on such finding.

The proposed action involves installing four LTAs, and as the NRC staff evaluated under the SE contained in ML23093A028, this action does not involve any significant changes in the types or significant increase in the amounts of any effluents that may be released offsite.

The proposed action involves installing four LTAs, and as the NRC staff evaluated under the SE contained in ML23093A028, this action does not involve any significant increase in individual or cumulative occupational exposure.

Based on the above, the NRC staff concludes that the proposed exemption meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's issuance of this exemption.

IV. Conclusions

Accordingly, the NRC has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances, pursuant to 10 CFR 50.12(a)(2)(ii), are present. Therefore, the NRC hereby grants SNC an exemption from the requirements of 10 CFR part 50, appendix K to allow the use of AXIOM fuel rod cladding material in LTAs 7ST1, 7ST2, 7ST3, and 7ST4 for up to two cycles of operation at Vogtle, Unit 2.

Dated at Rockville, Maryland, this 1st day of August, 2023.

For the Nuclear Regulatory Commission.

/RA/

Bo M. Pham,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2023–16755 Filed 8–4–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–424 and 50–425; NRC–2023–0093]

Southern Nuclear Operating Company; Vogtle Electric Generating Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to a request dated June 30, 2022, as supplemented by letters dated September 13, 2022, and January 20 and May 5, 2023, from Southern Nuclear Operating Company to allow the use of lead test assemblies (LTAs) 7ST1, 7ST2, 7ST3, and 7ST4, each with four fuel rods with a maximum nominal Uranium 235 (U–235) enrichment of up to six percent by weight for up to two cycles of operation at Vogtle Electric Generating Plant, Unit 2, and to receive, inspect, and store the LTAs at Vogtle, Units 1 and 2.

DATES: The exemption was issued on August 1, 2023.

ADDRESSES: Please refer to Docket ID NRC–2023–0093 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0093. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document

referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: John G. Lamb, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3100, email: *John.Lamb@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: August 2, 2023.

For the Nuclear Regulatory Commission.

John G. Lamb,

Senior Project Manager, Licensing Plant Branch 2–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption from 10 CFR 50.68(b)(7) to Allow the Use of Lead Test Assemblies, 7ST1, 7ST2, 7ST3, and 7ST4, each with four fuel rods with a maximum nominal Uranium 235 (U–235) enrichment of up to six percent by weight for up to two cycles of operation at Vogtle, Unit 2, and to receive, inspect, and store the LTAs at Vogtle, Units 1 and 2.

NUCLEAR REGULATORY COMMISSION

Docket Nos. 50–424, and 50–425

Southern Nuclear Operating Company

Vogtle Electric Generating Plant, Units 1 and 2

Exemption

I. Background

Southern Nuclear Operating Company (SNC, the licensee) is the holder of Facility Operating License Nos. NPF–68, and NPF–81, for the Vogtle Electric Generating Plant (Vogtle), Units 1 and 2, respectively. The licenses provide, among other things, that the licenses are subject to all rules, regulations, and orders of the Commission now or hereafter in effect.

The Vogtle, Units 1 and 2, consist of two pressurized-water reactors located at the licensee's site in Burke County, Georgia.

II. Request/Action

By letter dated June 30, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22181B156), as supplemented by letters dated September 13, 2022 (ML22256A198), and January 20 (ML23020A148) and May 5, 2023 (ML23125A269), SNC requested an exemption to title 10 of the *Code of Federal Regulations* (10 CFR), part 50, section 50.68, ''Criticality accident requirements,'' paragraph (b)(7) for Vogtle, Units 1 and 2.

Specifically, SNC requested an exemption from 10 CFR 50.68(b)(7) to allow the use of lead test assemblies (LTAs) 7ST1, 7ST2, 7ST3, and 7ST4 each with four fuel rods with a maximum nominal Uranium 235 (U–235) enrichment of up to six percent by weight for up to two cycles of operation at Vogtle, Unit 2, and allow receipt, inspection, and storage of the LTAs at Vogtle, Units 1 and 2.

The regulation at 10 CFR 50.68(b)(7) states, ''The maximum nominal U–235 enrichment of the fresh fuel assemblies is limited to five (5.0) percent by weight.''

III. Discussion

Pursuant to 10 CFR 50.12, the NRC may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, including 10 CFR 50.68(b)(7) when: (1) the exemptions are authorized by law, will not present an undue risk to the public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. Under 10 CFR 50.12(a)(2), special circumstances include, among other things, when application of the specific regulation in the particular circumstances would not serve, or is not necessary to achieve, the underlying purpose of the rule.

A. The Exemption is Authorized by Law

In accordance with 10 CFR 50.12, the NRC may grant an exemption from the requirements of 10 CFR part 50 if the exemption is authorized by law. The exemption requested in this instance is authorized by law, because no other prohibition of law exists to preclude the activities which would be authorized by the exemption.

This exemption would allow the licensee to insert four LTAs each containing four fuel rods with a maximum nominal U–235 enrichment of up to six percent by weight. A specific nominal U–235 enrichment in 10 CFR 50.68(b)(7) is at the discretion of the Commission consistent with its statutory authority. No statute required the NRC to adopt this specification. As stated above, 10 CFR 50.12 allows the Commission to grant exemptions from the requirements of 10 CFR part 50. The NRC staff has determined that granting of an exemption from 10 CFR 50.68(b)(7) related to nominal U–235 enrichment of up to six percent by weight will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

B. The Exemption Presents no Undue Risk to Public Health and Safety

SNC stated the following in its letter dated June 30, 2022:

The Vogtle reactors each contain 193 fuel assemblies. Each assembly consists of a matrix of 264 Zircaloy, ZIRLO®[TM], or Optimized ZIRLO®[TM] clad fuel rods with an initial composition of natural or slightly enriched uranium dioxide (UO2) as fuel material, not to exceed 5 wt% [weight-percent] enrichment. The proposed change is to load four LTAs with advanced ATF [accident-tolerant fuel] features, including ADOPT fuel [2], AXIOM cladding [3], chromium coating, and four rods per LTA with up to 6 wt% enrichment, in limiting core locations for up to two cycles of operation.

This exemption will not present an undue risk to public health and safety. The analysis performed in support of the enclosed LAR [license amendment request] addresses the safe storage of the LTAs. These were evaluated using AOR [analysis of record] plant-specific models to determine that existing storage configurations can be used for storage of the LTAs, with restrictions (see Section 3 above and Section 3.12 of Enclosure 1 [in letter dated June 30, 2022]). Thus, the granting of this exemption request will not pose an undue risk to public health and safety.

The licensee's requested exemption to paragraph 50.68(b)(7) is for the fuel rods enriched above 5.0 wt% U–235. Each LTA is limited to four rods at 6.0 wt% U–235. Those four rods add about 0.015% more U–235 to the LTAs relative to the Vogtle new fuel storage rack (NFSR) analysis of record (AOR) and the Vogtle spent fuel pool (SFP) AOR maximum enrichment of 5.0 wt% U–235. SNC's evaluation considered the fissile material increase due to the higher enrichment and that due to the higher fraction of the theoretical density of the ADOPT fuel. The licensee established Technical Specifications to control the storage of the LTAs. The NRC staff has found that these controls provide reasonable assurance that the four LTAs as described in SNC's amendment and exemption requests will meet 10 CFR 50.68(b)(2), 10 CFR 50.68(b)(3), and 10 CFR 50.68(b)(4). See the NRC staff evaluation (ML23093A028) for further details. Thus, the NRC staff finds that the requested exemption does not result in any undue risk to the public health and safety.

C. The Exemption is Consistent With the Common Defense and Security

The proposed exemption would allow the use of four LTAs, each with four fuel rods with a nominal U–235 enrichment of up to six percent by weight. This change to the plant core configuration has no impact on security issues. Special nuclear material in the LTAs will continue to be handled and controlled in accordance with applicable regulations. Therefore, the common defense and security is not impacted by this exemption.

D. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.68 is to provide reasonable assurance that an inadvertent criticality event will not occur during the storage or handling of special nuclear material at 10 CFR part 50 licenses. The preamble for the final rule promulgating 10 CFR 50.68 (**Federal Register**/Vol. 63, No. 218/Thursday, November 12, 1998/Rules and Regulations [[Page 63127]]) indicated that increases to the

enrichment limit of 5.0 wt% U–235 could be addressed in the future. In the safety evaluation (SE) contained in ML23093A028 for the license amendment request, the NRC staff evaluated for Vogtle, Units 1 and 2, four LTAs that demonstrated the acceptability of the nominal U–235 enrichment of up to six percent by weight of four fuel rods per LTA. The results showed that the LTAs would not adversely affect subcriticality in the spent fuel pool or new fuel storage racks. Therefore, the NRC staff concludes that application of 10 CFR 50.68(b)(7) in this particular circumstance is not necessary for the licensee to achieve the underlying purpose of the rule.

E. Environmental Considerations

With respect to its impact on the quality of the human environment, the NRC has determined that the issuance of the exemption discussed herein meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). The NRC staff's determination that all of the criteria for this categorical exclusion are met is as follows:

The regulation 10 CFR 51.22(c)(9) states:

Issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter that changes a requirement or issuance of an exemption from a requirement, with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter; or the issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter that changes an inspection or a surveillance requirement; provided that: (i) The amendment or exemption involves no significant hazards consideration; (ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and (iii) There is no significant increase in individual or cumulative occupational radiation exposure.

Staff Analysis: The exemption is from requirements with respect to the installation or use of facility components located within the restricted area as defined in 10 CFR part 20. The criteria for determining whether an action involves a significant hazards consideration are found in 10 CFR 50.92. The proposed action involves installed four LTAs. As stated in the evaluation in ML23093A028, the Commission has previously issued a proposed finding that the amendments involve no significant hazards consideration, published in the **Federal Register** on November 8, 2022 (87 FR 67508), and there has been no public comment on such finding.

The proposed action involves installing four LTAs, and as the NRC staff evaluated under the SE contained in ML23093A028, this action does not involve any significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

The proposed action involves installing four LTAs, and as the NRC staff evaluated under the SE contained in ML23093A028, this action does not involve any significant increase in individual or cumulative occupational exposure.

Based on the above, the NRC staff concludes that the proposed exemption meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's issuance of this exemption.

IV. Conclusions

Accordingly, the NRC has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances, pursuant to 10 CFR 50.12(a)(2)(ii), are present. Therefore, the NRC hereby grants SNC an exemption from the requirements of 10 CFR 50.68(b)(7) to allow the use of LTAs 7ST1, 7ST2, 7ST3, and 7ST4 each with four fuel rods with a nominal U–235 enrichment of up to six percent by weight, for up to two cycles of operation at Vogtle, Unit 2, and allow receipt, inspection, and storage of the LTAs at Vogtle, Units 1 and 2.

Dated at Rockville, Maryland, this 1st day of August, 2023.

For the Nuclear Regulatory Commission.

/RA/

Bo M. Pham,
Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2023–16753 Filed 8–4–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–425; NRC–2023–0091]

Southern Nuclear Operating Company; Vogtle Electric Generating Plant, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to a request dated June 30, 2022, as supplemented by letters dated September 13, 2022, and January 20, and May 5, 2023, from Southern Nuclear Operating Company to allow the use of AXIOM fuel rod cladding material in lead test assemblies 7ST1, 7ST2, 7ST3, and 7ST4, for up to two cycles of operation at Vogtle Electric Generating Plant, Unit 2.

DATES: The exemption was issued on August 1, 2023.

ADDRESSES: Please refer to Docket ID NRC–2023–0091 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0091. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: John G. Lamb, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3100; email: *John.Lamb@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: August 2, 2023.

For the Nuclear Regulatory Commission.

John G. Lamb,

Senior Project Manager, Plant Licensing Branch 2–1, Division of Operator Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption From 10 CFR 50.46 for Vogtle, Unit 2, To Allow the Use of AXIOM Fuel Rod Cladding Material in Lead Test Assemblies

Nuclear Regulatory Commission

Docket No. 50–425

Southern Nuclear Operating Company

Vogtle Electric Generating Plant, Unit 2

Exemption

I. Background

Southern Nuclear Operating Company (SNC, the licensee) is the holder of Facility Operating License No. NPF–81, for the Vogtle

Electric Generating Plant (Vogtle), Unit 2. The license provides, among other things, that the license is subject to all rules, regulations, and orders of the Commission now or hereafter in effect.

The Vogtle, Unit 2, consists of a pressurized-water reactor located at the licensee's site in Burke County, Georgia.

II. Request/Action

By letter dated June 30, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22181B156), as supplemented by letters dated September 13, 2022 (ML22256A198), January 20, 2023 (ML23020A148), and May 5, 2023 (ML23125A269), SNC requested an exemption to title 10 of the *Code of Federal Regulations* (10 CFR), part 50, section 50.46, ''Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors,'' for Vogtle, Unit 2.

Specifically, SNC requested an exemption from 10 CFR 50.46 to allow the use of AXIOM fuel rod cladding material in lead test assemblies (LTAs) 7ST1, 7ST2, 7ST3, and 7ST4 for up to two cycles of operation at Vogtle, Unit 2.

The regulation at 10 CFR 50.46(a)(1)(i) requires that, ''Each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircaloy or ZIRLO cladding must be provided with an emergency core cooling system (ECCS) that must be designed so that its calculated cooling performance following postulated loss-of-coolant accidents conforms to the criteria set forth in paragraph (b) of this section.'' The regulations make no provisions for use of fuel rods clad in a material other than zircaloy or ZIRLO.

III. Discussion

Pursuant to 10 CFR 50.12, the NRC may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, including 10 CFR 50.46, when: (1) the exemptions are authorized by law, will not present an undue risk to the public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. Under 10 CFR 50.12(a)(2), special circumstances include, among other things, when application of the specific regulation in the particular circumstances would not serve, or is not necessary to achieve, the underlying purpose of the rule.

A. The Exemption Is Authorized by Law

In accordance with 10 CFR 50.12, the NRC may grant an exemption from the requirements of 10 CFR part 50 if the exemption is authorized by law. The exemption requested in this instance is authorized by law, because no other prohibition of law exists to preclude the activities which would be authorized by the exemption.

This exemption would allow the licensee to insert four LTAs containing AXIOM fuel rod cladding that is neither Zircaloy nor ZIRLO, which are the cladding materials contemplated by 10 CFR 50.46(a)(1)(i). Selection of a specific cladding material in 10 CFR 50.46 was at the discretion of the Commission consistent with its statutory authority. No statute required the NRC to adopt this specification. As stated above, 10 CFR 50.12 allows the Commission to grant exemptions from the requirements of 10 CFR part 50. The NRC staff has determined that granting of an exemption from 10 CFR 50.46 related to AXIOM fuel rod cladding, which is neither Zircaloy nor ZIRLO, will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

B. The Exemption Presents No Undue Risk to Public Health and Safety

SNC stated the following in its letter dated June 30, 2022:

The Vogtle reactors each contain 193 fuel assemblies. Each assembly consists of a matrix of 264 Zircaloy, ZIRLO®[TM], or Optimized ZIRLO®[TM] clad fuel rods with an initial composition of natural or slightly enriched uranium dioxide (UO2) as fuel material, not to exceed 5 wt% [weight-percent] enrichment. The proposed change is to load four LTAs with advanced ATF [accident-tolerant fuel] features, including ADOPT fuel [2], AXIOM cladding [3], chromium coating, and four rods per LTA with up to 6 wt% enrichment, in limiting core locations for up to two cycles of operation.

This exemption will not present an undue risk to public health and safety. Reload evaluations ensure that acceptance criteria are met for the insertion of LTAs with fuel rods clad with AXIOM material. Due to similarities in the composition of the AXIOM alloy and the Optimized ZIRLO and standard ZIRLO alloys, fuel assemblies using AXIOM fuel rod cladding are evaluated using plant-specific models to address the changes in the cladding material properties. The LOCA [loss-of-coolant accident] safety analyses for VEGP [Vogtle Electric Generating Plant] are supported by the applicable site-specific Technical Specifications (TS). Reload cores are required to be operated in accordance with the operating limits specified in the TS. Thus, the granting of this exemption request will not pose an undue risk to public health and safety.[1]

Based upon the limited number of AXIOM clad fuel rods, the safeguards in place which would detect anomalous behavior, the use of NRC-approved models to ensure that all design criteria remain satisfied, and the requirement to operate the Vogtle, Unit 2, core within TS limits, the NRC staff finds the four LTAs acceptable for Vogtle, Unit 2. In conclusion, the NRC staff finds that the requested exemption does not result in any undue risk to the public health and safety, because NRC staff concluded that the existing LOCA evaluation models analysis of records for Vogtle are representative of the LTAs, and the presence of the LTAs will have a negligible impact on the co-resident fuel, and 10 CFR 50.46 acceptance criteria continue to be met. Further information can be found in the NRC staff safety evaluation (ML23093A028).

C. The Exemption Is Consistent With the Common Defense and Security.

The proposed exemption would allow the use of four LTAs with a variant cladding material. This change to the plant core configuration has no impact on security issues. Special nuclear material in the LTAs will continue to be handled and controlled in accordance with applicable regulations. Therefore, the common defense and security is not impacted by this exemption.

D. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.46 is to establish acceptance criteria for ECCS performance. In the safety evaluation (SE) contained in (ML23093A028) for the license amendment request, the NRC staff evaluated for Vogtle, Unit 2, four LTAs that demonstrated the acceptability of the AXIOM cladding under LOCA conditions. The unique features of the LTAs were evaluated for effects on the LOCA analyses. The results showed that the LTAs would not adversely affect ECCS performance. Therefore, the NRC staff concludes that application of the limitation to zircaloy and ZIRLO in 10 CFR 50.46 in this particular circumstance is not necessary for the licensee to achieve the underlying purpose of the rule.

E. Environmental Considerations

With respect to its impact on the quality of the human environment, the NRC has determined that the issuance of the exemption discussed herein meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). The NRC staff's determination that all of the criteria for this categorical exclusion are met is as follows:

The regulation 10 CFR 51.22(c)(9) states:

Issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter that changes a requirement or issuance of an exemption from a requirement, with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter; or the issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter that changes an inspection or a surveillance requirement; provided that: (i) The amendment or exemption involves no significant hazards consideration; (ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and

(iii) There is no significant increase in individual or cumulative occupational radiation exposure.

Staff Analysis: The exemption is from requirements with respect to the installation or use of facility components located within the restricted area as defined in 10 CFR part 20. The criteria for determining whether an

[1] Although this quoted material states that the LTAs would be placed in limiting core locations, SNC's May 5, 2023, supplement, states that the LTAs will not be placed in core regions that have been shown to be limiting with respect to the control rod ejection analysis.

action involves a significant hazards consideration are found in 10 CFR 50.92. The proposed action involves installed four LTAs. As stated in the evaluation in ML23093A028, the Commission has previously issued a proposed finding that the amendments involve no significant hazards consideration, published in the **Federal Register** on November 8, 2022 (87 FR 67508), and there has been no public comment on such finding.

The proposed action involves installing four LTAs, and as the NRC staff evaluated under the SE contained in ML23093A028, this action does not involve any significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

The proposed action involves installing four LTAs, and as the NRC staff evaluated under the SE contained in ML23093A028, this action does not involve any significant increase in individual or cumulative occupational exposure.

Based on the above, the NRC staff concludes that the proposed exemption meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's issuance of this exemption.

IV. Conclusions

Accordingly, the NRC has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances, pursuant to 10 CFR 50.12(a)(2)(ii), are present. Therefore, the NRC hereby grants SNC an exemption from the requirements of 10 CFR 50.46 to allow the use of AXIOM fuel rod cladding material in LTAs, 7ST1, 7ST2, 7ST3, and 7ST4, for up to two cycles of operation at Vogtle, Unit 2.

Dated at Rockville, Maryland, this 1st day of August, 2023.

For the Nuclear Regulatory Commission.

/RA/

Bo M. Pham,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2023–16756 Filed 8–4–23; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0226, It's Time To Sign Up for Direct Deposit or Direct Express, RI 38–128

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM), Retirement Services, offers the general public and other Federal agencies the opportunity to comment on an expiring information collection request (ICR), RI 38–128—It's Time to Sign Up for Direct Deposit or Direct Express, without change.

DATES: Comments are encouraged and will be accepted until September 6, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *http://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''*Currently under Review—Open for Public Comments*'' or by using the search function or fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0226) was previously published in the **Federal Register** on May 3, 2023, at 88 FR 27927, allowing for a 60-day public comment period. No comments were received for this collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 38–128, It's Time to Sign Up for Direct Deposit or Direct Express, provides the opportunity for the annuitant to elect Direct Deposit or Direct Express. This election is required only once: when a person is first put on our annuity roll. If there is no evidence that the separating agency gave the person this election, OPM must provide RI 38–128.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: It's Time to Sign Up for Direct Deposit or Direct Express.

OMB Number: 3206–0226.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 20,000.

Estimated Time per Respondent: 30 minutes.

Total Burden Hours: 10,000.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2023–16801 Filed 8–4–23; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Agency Information Collection Activities; Proposals, Submissions, and Approvals: Questionnaire for National Security Positions

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Office of Personnel Management (OPM) requests clearance from the Office of Management and Budget (OMB) on the renewal of a previously approved information collection request (ICR), Questionnaire for National Security Positions, Standard Form 86 (SF 86), which is completed by civilian employees of the Federal Government, military personnel, and non-Federal employees who perform work for or on behalf of the Federal Government.

DATES: Comments are encouraged and will be accepted until September 6, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by email to *SuitEAforms@opm.gov,* or by contacting Alexys Stanley, 202–606–1800, or U.S. Office of Personnel Management, Suitability Executive Agent Programs, P.O. Box 699, Slippery Rock, PA 16057.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0005) was previously published in the **Federal Register** on May 25, 2023, at 88 FR 33943, allowing for a 60-day public comment period. No comments were received.

The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Background

The Questionnaire for National Security Positions, Standard Form 86 (SF 86) is completed by civilian employees of the Federal Government, military personnel, and non-Federal employees who perform work for or on behalf of the Federal Government. For applicants for civilian Federal employment, the SF 86 is to be used only after a conditional offer of employment has been made. The Electronic Questionnaires for Investigations Processing (e-QIP) and National Background Investigation Systems (NBIS) are web-based applications that house the SF 86. A variable in assessing burden hours is the nature of these electronic applications. The electronic applications include branching questions and instructions which provide for an efficient collection of information from the respondent based on varying factors in the respondent's personal history. The burden on the respondent is reduced when the respondent does not have personal history relevant to particular questions. Therefore, the questions do not expand for additional details.

OPM recommends renewal of the form without any proposed changes. This recommendation is due to the forthcoming plan to replace the SF 86 with the Personnel Vetting Questionnaire, which is currently under review for approval by the Office of Management and Budget (87 FR 71700 and 88 FR 12703).

Analysis

Agency: Office of Personnel Management.

Title: Questionnaire for National Security Positions, Standard Form 86 (SF 86).

OMB Number: 3206–0005.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 470,124.

Estimated Time per Respondent: 150 minutes.

Total Burden Hours: 1,175,310.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2023–16806 Filed 8–4–23; 8:45 am]

BILLING CODE 6325–66–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2022–88; CP2023–104]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 8, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2022–88; *Filing Title:* USPS Notice of Amendment to Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 16, Filed Under Seal; *Filing Acceptance Date:* July 31, 2023; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* August 8, 2023.

2. *Docket No(s).:* CP2023–104; *Filing Title:* USPS Notice of Amendment to Priority Mail, Parcel Select & Parcel Return Service Contract 1, Filed Under Seal; *Filing Acceptance Date:* July 28, 2023; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* August 8, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–16728 Filed 8–4–23; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98033; File No. SR–NYSEARCA–2023–48]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend a Representation Regarding the VanEck Merk Gold Trust

August 1, 2023.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 19, 2023, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend a representation regarding the VanEck Merk Gold Trust. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission has previously approved a proposed rule change relating to listing and trading on the Exchange of shares of the Trust (the ''Shares'') under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares).[4] The Commission subsequently noticed for immediate effectiveness a proposed rule change to replace references to the ''London Gold Fix'' in the Prior Order with the ''LBMA Gold Price.'' [5] Pursuant to the Prior Notice, the Trust currently uses the LBMA Gold Price as the benchmark price for purposes of calculating the net asset value (''NAV'') of the Shares of the Trust.

The Exchange now proposes to amend the representation in the Prior Notice to replace references to the ''LBMA Gold Price'' with the ''Solactive Gold Spot Index'' (the ''Index''). Pursuant to this proposed rule change, the Trust would use the Solactive Gold Spot Index as the benchmark price for purposes of calculating the NAV of Shares of the Trust.

According to the Trust's current registration statement on Form S–3,[6] Solactive AG (''Solactive'' or the ''Index Calculator'') owns, calculates, and disseminates the Index. The Index is a U.S. Dollar denominated index that aims to provide a price fixing for the gold spot price for London delivery gold bullion quoted as U.S. Dollars per Troy Ounce (''XAU'') and determined as of the time trading closes on the New York Stock Exchange (''NYSE'').[7] The Index calculates gold bullion fixing prices by taking Time Weighted Average Prices (''TWAP'') [8] of XAU trading prices provided via ICE Data Services (''IDS'') data feed.[9]

Specifically, according to the Registration Statement, the Index uses a TWAP calculation to determine an average price that is time-weighted, using prices of actual transactions (''Trade Ticks'') for two specified time periods around the scheduled close of trading on the NYSE (generally, 4:00 p.m. Eastern Time) on each day that the NYSE is open for trading.[10] The TWAP is derived for (1) the period ahead of the fixing (''Time Period 1''), which consists of the five minutes before the close of trading, and (2) the period directly after the fixing (''Time Period 2''), which consists of the six seconds after the close of trading. The TWAPs for Time Period 1 and Time Period 2 are each multiplied by their respective weightings, with 90% weighting given to Time Period 1 and 10% weighting given to Time Period 2. When added together, the two TWAPs result in a

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 71378 (January 23, 2014), 79 FR 4786 (January 29, 2014) (SR–NYSEArca–2013–137) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To List and Trade Shares of the Merk Gold Trust Pursuant to NYSE Arca Equities Rule 8.201) (the ''Prior Order'').

[5] *See* Securities Exchange Act Release No. 74544 (March 19, 2015), 80 FR 15840 (March 25, 2015) (SR–NYSEArca–2015–19) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the LBMA Gold Price as a Replacement for the London Gold Fix for Certain Gold Related Exchange Traded Products) (the ''Prior Notice'').

[6] On May 12, 2023, the Trust filed Post-Effective Amendment No. 1 to its registration statement on Form S–3 (the ''Registration Statement'') (File No. 333–238022).

[7] Solactive calculates the Index pursuant to the Index Guideline publicly available at *https://www.solactive.com/wp-content/uploads/2023/02/Solactive_Gold_Spot_Index_Methodology_Guideline_20230206.pdf.* Index data are publicly available at *https://www.solactive.com/indices/?index=DE000SL0FW35.*

[8] TWAP is a widely used measure in the financial industry to calculate the average price of a security or traded asset over a specific time period. TWAP is calculated by dividing the total trade value by the total trading time, thereby providing an average price that reflects market conditions over a defined timeframe. The TWAP methodology helps mitigate the impact of large trades on market prices by providing an average price based on numerous current market transactions and mitigates the effects of erroneous or spurious pricing data points, which effects can significantly lower the level of confidence in single transaction data points at a specific time. Different weightings can be selected for the TWAP methodology to provide a check on average prices derived before a local market closing, for instance, by overweighting prices immediately after the local market close.

[9] Solactive receives real-time data via IDS's ''Spot Gold (Also Loco London Gold)'' data feed. The spot gold prices utilized by the Index are those for gold bullion deliverable in London. The Trust's gold is also valued on a loco London basis.

[10] The NYSE's trading hours and holidays observed are available at: *https://www.nyse.com/markets/hours-calendars.*

single price sum that is the Index price.[11]

For any calculation day *t,* the Index ($Index_t$), is determined as described above following the below mathematical formula:

$$Index_t = 0.9 * TWAP^{XAU}_{t,\ \text{TWAP Fixing Start Time},\ \text{TWAP End Time}} + 0.1 * TWAP^{XAU}_{t,\ \text{TWAP End Time},\ \text{TWAP Fixing End Time}}$$

With:

$$Index_{\text{Start Date}} = 100$$

$$TWAP^{XAU}_{t,\ \text{Time Period 1}} = \frac{\sum_{k=1}^{k=N} P^{XAU}_{t,k}}{N1}$$

$$TWAP^{XAU}_{t,\ \text{Time Period 2}} = \frac{\sum_{k=1}^{k=N} P^{XAU}_{t,k}}{N2}$$

Time Period 1 : The Time Period between Twap Fixing Start Time and Twap End Time.

Time Period 2 : The Time Period between Twap End Time and Twap Fixing End Time.

N1: Total Number of Ticks in the Time Period 1 as of the Calculation Day t.

N2: Total Number of Ticks in the Time Period 2 as of the Calculation Day t.

$P^{XAU}_{t,k}$: The Tick Value (using TRADE ticks) of XAU corresponding to the Tick number ***k*** as ***t.***

The sponsor of the Trust, Merk Investments LLC (the ''Sponsor''), believes that the Index will provide an improved benchmark price for purposes of determining the NAV of Shares of the Trust. Specifically, the Sponsor believes that replacing the LBMA Gold Price with the Index for calculating the NAV of the Shares may reduce the impact of timing differences between the basis for NAV calculation and market price for the Shares, as well as promote market liquidity, and would promote consistency between the NAV calculation and market price of the Shares by shifting the gold spot price determination to the end of the NYSE trading day (including because a significant amount of gold bullion trading (loco London) occurs after the close of London bullion trading). In addition, the Sponsor does not expect that the adoption of the Index will result in any unexpected, abrupt, or radical change in the value of the Trust's gold because both the LBMA Gold Price and the Index report the price in U.S. Dollars of a Troy Ounce of gold bullion deliverable in London, just at different times.

According to the Registration Statement, the LBMA Gold Price is calculated by the ICE Benchmark Administration (the ''IBA''), which determines a gold price fixing for the London bullion market. Whereas the LBMA Gold Price is calculated twice daily (at 10:30 a.m. London Time and 3:00 p.m. London Time), the Index is calculated once daily no later than 30 minutes after the close of trading at the NYSE, which timing is more closely aligned with the close of trading in the Shares on a given trading day.[12] Whereas the LBMA Gold Price is determined through an auction process involving a varying daily group of participants (currently, representing a subset of 16 direct participants) and is conducted by the IBA,[13] the Index is calculated by Solactive based on thousands of transaction prices for gold bullion spot during Time Periods 1 and 2, as captured by IDS from identifiable and IDS-accepted data contributors.[14] As noted above, while both the LBMA Gold Price and the Index price represent actual transactions in London gold bullion spot, they mainly differ in the timing of the fixing window.

The LBMA Gold Price and the Index are based on the same London delivery gold spot, but at different times from a larger 24-hour market trading period. Both the LBMA Gold Price and the Index establish gold bullion spot prices loco London taken from the same continuous stream of data for such prices and differ only in that they reflect different snapshots at different times.[15] On the same day, the LBMA Gold Price and the Index price may differ because of changes in the conditions of the gold spot market between the two different fixing times. However, when such price moves occur, use of the Index as a benchmark would facilitate the calculation of an NAV for Shares of the Trust that is aligned with and accounts for activity around the close of trading in such Shares. The Sponsor thus believes that using the Index rather than the LBMA Gold Price as the benchmark to calculate the NAV of the Shares could provide a timelier value of the NAV calculation and promote consistency between the NAV and market price of the Shares.[16]

The Sponsor believes that using the Index, which is calculated based on timing that better mirrors the trading hours of the Shares, to calculate the NAV of the Shares would be beneficial for market makers and liquidity providers for the Shares by allowing them to manage their overnight risk exposure more effectively. The Sponsor has analyzed the daily trading volume of the Shares between November 16, 2022 and May 30, 2023, as measured in five minute increments. This analysis revealed that, over the 133 trading days

[11] The Sponsor believes that it is unlikely that, on any given trading day for the Shares, there would be no Trade Ticks recorded for XAU in either Time Period 1 or Time Period 2, such that the Index calculation could not be performed on such day. Trade Ticks representing XAU are the closing prices for London delivery gold bullion transactions posted in a 24-hour, global, over-the-counter gold bullion market, which is not subject to trading suspensions, trading halts, or market closures. Trade Ticks in Time Periods 1 and 2 thus reflect a comprehensive view of the gold spot market for London delivery gold that includes more market participants than the LBMA Gold Price. In the unlikely event that IDS is unable to publish pricing information for XAU, for whatever reason, during either Time Period 1 or Time Period 2 on a given trading day, the last available Index calculation will be used in accordance with Solactive's published and publicly available disruption policy.

[12] The Trust currently utilizes the 3:00 p.m. London Time LBMA Gold Price and only resorts to the 10:30 a.m. London Time LBMA Gold Price if the afternoon price is not available.

[13] IBA operates the technology platform that facilitates the electronic auction process to determine the LBMA Gold Price.

[14] Contributors to the data feed include national central banks, large international banks that are recognized gold bullion trading or custody banks, and international bullion trading firms.

[15] LBMA Gold Prices are reflected in the XAU data feed utilized by the Index (although they are reported outside of the Index's Time Periods 1 and 2).

[16] Shares of the Trust are only created and redeemed in kind.

during this period, Share trading volume was on average 17.2% higher in the five minutes before the close of trading on the NYSE than during the rest of the trading day. As expected, the analysis revealed that Share trading volume is also generally higher when London and New York trading overlap, but that there was a consistent and significant increase in Share trading volume immediately before the close of trading on the NYSE. Increased trading before market close generally reflects hedging in the Shares by market makers and other major market participants to mitigate overnight market risk arising from their exposure to the Shares. The relative staleness of the LBMA Gold Price at the time the Trust calculates its NAV contributes to the uncertainty that major market participants contend with in managing their overnight market risk, which could result in lower liquidity for the Shares.

Market risk uncertainty is further heightened on days when the London gold bullion market is closed altogether, but the Shares continue to trade on the NYSE. Further, whereas the IBA observes a U.K. banking holiday schedule, the Shares of the Trust are traded on the Exchange, which observes a U.S. market calendar. As a result, there are days on which the IBA does not hold an auction because the U.K. markets are closed, but the Shares continue to trade on the Exchange. On such days and on days when there is significant movement in the market between the calculation of the LBMA Gold Price and the close of trading in the Shares, the NAV of the Shares of the Trust is not updated, while the market pricing of Shares of the Trust will generally continue to reflect activity in the gold spot market represented by XAU. In addition, in some cases, an NAV based on a stale LBMA Gold Price may give the perception of tracking error when none exists.

Aligning the calculation of the NAV of the Shares with the close of trading in the Shares would also promote a NAV calculation that takes into account important liquidity events because the close of NYSE trading is generally the most liquid time of the trading day for Shares of the Trust. Closing the timing gap between the Trust's benchmark price determination and the close of trading in the Shares and subsequent NAV calculation could improve liquidity in the Shares by enabling market makers and liquidity providers to better manage risk and help reduce investor confusion stemming from any erroneous perceived tracking error. Moreover, market participants, including market makers, are unlikely to be confused or otherwise negatively impacted by the Trust's use of the Index instead of the LBMA Gold Price. Instead, because market participants already primarily rely on the gold spot price represented by XAU to inform their trading of Shares, the proposed change to the Index would align with current market participant expectations on how to value the Trust's gold.

The Sponsor believes that the Index is a suitable replacement for the LBMA Gold Price because it would provide a reliable benchmark for purposes of calculating the NAV of the Shares and a better pricing mechanism in times of market volatility. Specifically, the Sponsor believes that the Index's methodology is reasonably designed to be resistant to potential price manipulation because the Index is based on an average spot price that is time-weighted around the close of trading on the NYSE. As described above, the Index's methodology aims to reflect a closing price for XAU that would be observed at the conclusion of a trading day in Shares of the Trust. By using TWAPs that account for the five minutes leading up to and six seconds immediately following the market close rather than using a single Trade Tick at the exact close, the Index's methodology is intended to minimize the impact of any attempts to manipulate the fixing price by submitting single time orders or any erroneous orders that could result in a NAV that does not fairly reflect the value of the Trust's gold.

In addition, the Index Provider is registered as a benchmark administrator under European Benchmarks Regulation (''BMR'') with the German Federal Financial Supervisory Authority and adheres to the IOSCO Principles for Financial Benchmarks (''IOSCO Principles'').[17] The BMR requires the Index Provider to have in place a control framework that ensures its benchmarks within scope of the BMR are provided or published and made available in accordance with the BMR. The control framework provides a description of the control activities and further information on how the business and the processes relate to the requirements of the BMR. The Index Provider has an Oversight Committee that is responsible for the integrity of the administration process and oversees its control framework for the process of determining and distributing the indices and benchmarks. The Index Provider is thus subject to a similar level of regulatory scrutiny as the IBA is with respect to the LBMA Gold Price,[18] and, while the Index itself is not a BMR-compliant benchmark, the Index Provider applies the same processes and procedures in calculating the Index as it does to its BMR-compliant benchmarks, including ensuring that the price discovery process for the Index is subject to surveillance by the Index Provider and is auditable and transparent in accordance with the IOSCO Principles (as further discussed below).

Further, the Index is derived from data recorded during Time Periods 1 and 2—a total period of five minutes and six seconds. Thus, the Index calculation reflects several thousand Trade Ticks of actual transactions from hundreds of identifiable and IDS-accepted data contributors for a given calculation day. The Sponsor believes that the broad base of data underlying the Index calculation reduces the potential for price manipulation affecting NAV calculation.

The Sponsor also believes that the Index would provide enhanced transparency to the calculation of the NAV of the Shares. The Index will be calculated and published by the Index Calculator no later than 30 minutes following the close of trading on the NYSE on each business day, disseminated to major financial data providers, and made publicly available via the Trust's website. Solactive has published publicly available guidelines that outline the methodology for the Index calculation, including the formula by which the Index is calculated, such that the calculation could be replicated by anyone with access to the underlying XAU market data. Underlying XAU market data is commonly and broadly

[17] *See https://www.iosco.org/library/pubdocs/pdf/IOSCOPD415.pdf.* The IOSCO Principles are designed to enhance the integrity, the reliability and the oversight of benchmarks by establishing guidelines for benchmark administrators and other relevant bodies in the areas of (1) governance: to protect the integrity of the benchmark determination process and to address conflicts of interest; (2) quality of the benchmark: to promote the quality and integrity of benchmark determinations through the application of design factors; (3) quality of the methodology: to promote the quality and integrity of methodologies by setting out minimum information that should be addressed within a methodology; and (4) accountability mechanisms: to establish complaints processes, documentation requirements and audit reviews. The IOSCO Principles provide a framework of standards that might be met in different ways, depending on the specificities of each benchmark. In addition to a set of high-level principles, the framework offers a subset of more detailed principles for benchmarks having specific risks arising from their reliance on submissions and/or their ownership structure. The IOSCO Principles also call for credible transition policies in case a benchmark may cease to exist due to market structure change.

[18] IBA is compliant with the UK benchmark regulation (MAR 8.3), regulated by the FCA, and has been formally assessed against the IOSCO Principles.

available to a wide group of market participants, including analysts, advisers, traders, and investors at broker-dealers, banks, trading platforms, investment advisers and other financial institutions and investors that trade in gold bullion, as well as to the market makers and authorized participants for the Shares. The Sponsor believes that the Index provides a benchmark that is comprehensible and easily accessible to a wide range of market participants, thus promoting transparency into the valuation process for Shares of the Trust.[19]

Finally, the Sponsor believes that the Index would provide a comprehensive benchmark for purposes of determining the NAV of the Shares of the Trust. The Index calculation is based on XAU market data from IDS, which is a major provider of financial market data to institutions including banks and other asset managers for the pricing of portfolio assets and the execution of asset transactions. Various spot data, including XAU, is available through IDS's data streaming service, which covers 2,700 spot rates, with an average of over 130 million updates per day for all spots provided by IDS. IDS compiles data from over 100 sources, including market makers, execution venues, banks and brokers from across the globe, and every updating Trade Tick of spot streaming data is available via IDS's Integrated Data Viewer service in a file-based format.

The Sponsor believes that data aggregated by IDS provides a reliable basis for the calculation of the Index given the robust quality control and filtering process IDS applies to XAU Trade Ticks to exclude outliers and erroneous pricing. IDS publishes a ''Consolidated Feed Wires Protocol'' applicable to XAU and other IDS data feeds (the ''Protocol''). The Protocol specifies the data series that are associated with XAU.[20] Data in these series include millisecond time-stamped trade prices of XAU submitted by identifiable and IDS-accepted contributors, and Solactive extracts Trade Ticks from this data set to calculate the Index. IDS's automated processes evaluate XAU trade price contributions to determine the authenticity of the contributor and the validity of the trade price contribution as representative of actual transaction pricing based on contemporary and historical XAU data fields. IDS data evaluation and data integrity processes are designed to filter out any invalid Trade Ticks.

In addition, the Index Provider verifies input data used in the calculation of the Index to ensure the continuous quality of such data, including through automated assessments at the individual data value level as well as plausibility checks at the aggregated index level. The Index Provider also takes supplementary quality control measures by performing in-depth analyses of selected data samples in longer intervals to facilitate additional scrutiny of the data and detection of conduct indicating potential data manipulation. Finally, the Index Provider maintains long-term records of the input data used for each Index determination in order to be able to verify a determination retrospectively.

The Exchange believes the Index will serve as an appropriate replacement to the LBMA Gold Price for purposes of determining the NAV of Shares of the Trust. The Index will be operated by a regulated benchmark administrator and its methodology is transparent, replicable, and auditable. The Index would provide a sound and reasonable basis for the calculation of an NAV that reflects the same gold bullion spot price loco London as the LBMA Gold Price (and thus would generally be very similar to the LBMA Gold Price), but that is more closely aligned with the timing of trading in the Shares. Accordingly, the Index is likely to facilitate a fairer NAV calculation for Shares of the Trust, particularly when market conditions include significant price moves in gold between when the LBMA Gold Price is calculated versus the New York trading close. The Exchange also believes that the Index is an appropriate replacement for the LBMA Gold Price given the anticipated benefits of aligning the timing of the Index calculation with the daily close of trading in the Shares of the Trust, including promoting liquidity by permitting market makers and other liquidity providers to more efficiently manage their risk and promoting consistency with market participants expectations' on how to value the Trust's gold.

In connection with this proposed rule change, the Sponsor will:

(1) issue a press release informing the public of the date on which the Trust will first use the Index to calculate its NAV;

(2) file the applicable press release with the Commission by means of Form 8–K, which will be available on the Trust's website; and

(3) file an amendment to its registration statement relating to the proposed change.[21]

Except for the change noted above, all other representations made in the Prior Order and Prior Notice remain unchanged, and the Trust will continue to comply with all initial and continued listing requirements.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[22] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Index will be calculated via a robust and transparent methodology, based on high-quality transaction data from a major financial data provider. The Exchange believes the Index will serve as an appropriate replacement to the LBMA Gold Price for purposes of determining the NAV of the Shares and will provide a sound and reasonable basis for calculation of NAV that is more closely aligned with U.S. trading hours, which would protect investors and the public interest by promoting liquidity and price stability of Shares of the Trust and reduce investor confusion arising from any perceived tracking error based on the timing of the LBMA Gold Price fixing vis a vis the calculation of the Shares' NAV. Specifically, although the LBMA Gold Price and Index price are typically very similar and both reflect gold bullion spot prices loco London, the Index is likely to facilitate a fairer NAV calculation for Shares of the Trust in general and, particularly, on days where there have been significant price moves in gold between when the LBMA Gold Price is calculated versus the New York trading close and would allow the calculation of an NAV on every day that Shares of the Trust trade on the

[19] By contrast, the LBMA Gold Price auction process lacks an equivalent degree of transparency because no direct participant in the daily electronic auction or any other bullion market participant can independently recreate how the auction resulted in a particular price.

[20] The data series set for XAU reports, among other data: trade price; ask price; bid price; current price; millisecond Unix time stamps of last trade/quote update, last trade and last quote; contributor code; city code; region code; high; low; open; and change from yesterday. Solactive uses the trade price data series to calculate the Index. IDS uses the other data received to perform automated quality control checks of each trade price submitted by a contributor.

[21] The Sponsor further represents that it will manage the Trust as described in the Prior Order and Prior Notice and will not implement the changes described herein until the amendment to its registration statement and this proposed rule change are effective and operative.

[22] 15 U.S.C. 78f(b)(5).

Exchange. In addition, the Index, which is calculated in alignment with the close of trading in the Shares on each trading day, provides a pricing mechanism better equipped to respond to market volatility and that includes liquidity at the close of trading in the Shares in an assessment of their NAV. Moreover, because the Index would reflect the gold spot price as represented by XAU, market participants—who already primarily refer to such price to inform their trading in Shares of the Trust—would not be impacted negatively by the proposed change. Instead, because market participants already primarily rely on the gold spot price represented by XAU to inform their trading of Shares, the proposed change to the Index could remove impediments to, and perfect the mechanism of, a free and open market by promoting consistency with current market participant expectations on how to value the Trust's gold.

The proposed rule change is also designed to perfect the mechanism of a free and open market price discovery process and, in general, to protect investors and the public interest because the Index will be administered and disseminated by Solactive, which is unaffiliated with the Sponsor and the Trust, and the Index will be transparent, auditable, and operated by a regulated benchmark administrator that adheres to IOSCO Principles. The guidelines that outline the methodology for the Index calculation are publicly available, including the formula by which the Index is calculated, such that the calculation could be reproduced by anyone with access to the underlying XAU market data, which is itself widely available to market participants. XAU data underlying the Index are submitted by identifiable and IDS-accepted contributors, and IDS evaluates XAU trade price contributions to determine the authenticity of the contributor and the validity of the trade price contribution as representative of actual transaction pricing based on contemporary and historical XAU data fields, as well as to identify and filter out any invalid Trade Ticks. In addition, although the Index is not a BMR-compliant benchmark, the Index Provider applies the same processes and procedures to the Index as it does to its BMR-compliant benchmarks; accordingly, the Index is subject to surveillance and other quality control measures performed by the Index Provider, including data analysis to aid in the identification of conduct indicating potential data manipulation and maintenance of records allowing the Index Provider to verify historical Index determinations. The Trust will continue to be listed and traded on the Exchange pursuant to the initial and continued listing criteria set forth in NYSE Arca Rule 8.201–E. Except for the changes noted above, all other facts presented and representations made in Prior Order and Prior Notice remain unchanged.[23]

As noted above, prior to implementing the proposed change, the Sponsor will (1) issue a press release informing the public of the date the Trust will first use the Index to calculate the NAV of the Shares; (2) file the applicable press release with the Commission by means of Form 8–K, which will be available on the Trust's website; and (3) file an amendment to the Trust's registration statement relating to the proposed change. The Exchange believes that such press release and registration statement amendment will protect investors and the public interest by providing notification to investors of the new gold price benchmark prior to the use of the Index by the Trust. The Exchange also believes that the proposed change is designed to protect investors and the public interest because, except for the change noted above with respect to the Index as the new benchmark for the calculation of the NAV for the Shares of the Trust, all other representations made in the Prior Order and Prior Notice remain unchanged, and the Trust will continue to comply with all initial and continued listing requirements.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue, but rather would permit the Trust to update the benchmark it uses for purposes of calculating the NAV of Shares from the LBMA Gold Price to the Index. The Exchange does not believe this change will impact intramarket or intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

[23] *See* notes 4 & 5, *supra*.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[24] and subparagraph (f)(6) of Rule 19b–4 thereunder.[25]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[26] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change would amend a representation to replace references to the LBMA Gold Price as the benchmark for NAV calculation with references to the Index, which, for reasons discussed above, the Exchange believes is a suitable replacement. Other than amending that representation as specifically discussed herein, all statements in the Prior Order and Prior Notice remain unchanged, and the Trust will continue to comply with all initial and continued listing requirements. For these reasons, and because the proposal raises no novel legal or regulatory issues, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[27]

[24] 15 U.S.C. 78s(b)(3)(A)(iii).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEARCA–2023–48 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2023–48. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2023–48 and should be submitted on or before August 28, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–16712 Filed 8–4–23; 8:45 am]

BILLING CODE 8011–01–P

efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98032; File No. SR–ICEEU–2023–013]

Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Amendments to the Collateral and Haircut Procedures

August 1, 2023.

I. Introduction

On June 9, 2023, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4,[2] a proposed rule change to amend the ICE Clear Europe Collateral and Haircut Procedures (the ''Procedures''). The proposed rule change was published for comment in the **Federal Register** on June 26, 2023.[3] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

ICE Clear Europe is registered with the Commission as a clearing agency for the purpose of clearing security-based swaps. In its role as a clearing agency for security-based swaps, ICE Clear Europe provides services to its Clearing Members and Clearing Members transfer assets to ICE Clear Europe.[4] For example, ICE Clear Europe's Clearing Members transfer to ICE Clear Europe cash and other assets as collateral to cover the exposures presented by the positions that ICE Clear Europe clears. ICE Clear Europe communicates such collateral requirements as Initial Margin and Guaranty Fund requirements.[5] ICE Clear Europe generally refers to the assets that it accepts from Clearing Members to cover their Initial Margin and Guaranty Fund requirements as Permitted Cover.[6]

The Procedures describe ICE Clear Europe's operational activities and related governance processes with respect to Permitted Cover. These operational activities include, among other things, enforcing basic eligibility criteria that assets must satisfy to be Permitted Cover, valuing Permitted Cover, and applying haircuts to that value.[7]

The proposed rule change relates to the eligibility criteria that ICE Clear Europe uses to determine whether to accept a particular asset as Permitted Cover. Section 2 of the Procedures sets out the general criteria that all assets must satisfy to be considered Permitted Cover. Among other things, to be considered Permitted Cover an asset must be highly liquid with an active sale or repurchase agreement market with a diverse group of buyers and sellers.

In addition to the general criteria found in Section 2, which applies to all assets submitted as Permitted Cover, Appendix A to the Procedures provides additional eligibility criteria for two specific asset classes: financial instruments and gold. To qualify as

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the Collateral Haircut Procedures, Exchange Act Release No. 97766 (June 20, 2023); 88 FR 41439 (June 26, 2023) (SR–ICEEU–2023–013) (''Notice'').

[4] Capitalized terms not otherwise defined herein have the meanings assigned to them in the Procedures or the ICE Clear Europe Clearing Rules.

[5] ICE Clear Europe's Clearing Rules note that Initial Margin means ''the Permitted Cover required to be provided or actually provided . . . to the Clearing House as collateral for the obligations of a Clearing Member or Sponsored Principal in respect of CDS Contracts . . . .'' ICE Clear Europe Clearing Rule 101. Guaranty fund contributions serve to secure the obligations of a Clearing Member to ICE Clear Europe and may be used to cover losses sustained by ICE Clear Europe in the event of a default of the Clearing Member. ICE Clear Europe Clearing Rule 1103.

[6] ICE Clear Europe Rule 101 defines ''Permitted Cover'' as ''. . . cash in Eligible Currencies and other assets determined by the Clearing House as permissible for Margin or Guaranty Fund Contributions and includes, where the context so requires, any such cash or assets transferred to the Clearing House and any proceeds of realisation of the same. A particular kind of currency or asset may be determined by the Clearing House to be Permitted Cover only in respect of Proprietary Accounts, particular kinds of Customer Accounts, Energy Contracts, Financials & Softs Contracts, F&O Contracts, FX Contracts, CDS Contracts or certain Sets of Contracts.''

[7] ICE Clear Europe uses these haircuts to reduce the value of the Permitted Cover. Doing so helps account for a potential decline in value that ICE Clear Europe could face if it had to liquidate the Permitted Cover in stressed market conditions.

Permitted Cover, financial instruments and gold must satisfy both the general eligibility criteria in Section 2 and the specialized criteria in Appendix A.

The proposed rule change would amend the specialized criteria for gold found in Appendix A. Currently ICE Clear Europe will accept gold as Permitted Cover in either of the following circumstances: (i) the gold is owned as allocated gold bullion, meaning ICE Clear Europe directly owns an interest in specific gold bars or (ii) the gold is owned as unallocated gold bullion through a firm with low credit risk based on ICE Clear Europe's own assessment. Unallocated means ICE Clear Europe owns an interest in a pool of gold bars rather than specific gold bars. Thus, unallocated gold represents a claim against the relevant custodian for an amount of metal held in bulk, while allocated gold held by a custodian is specifically identified for a particular owner. The proposed rule change would delete the unallocated option. Under Appendix A as amended, ICE Clear Europe would only accept gold if it is specifically allocated to ICE Clear Europe.

Specifically, the amended Appendix A would state that ICE Clear Europe would only recognize gold as Permitted Cover where the gold is transferred from an unallocated account to an allocated account of a custodian in the name of ICE Clear Europe. Once the gold meets those criteria, it will be deemed to be allocated pure gold bullion of recognized good delivery.

This amendment would help to ensure that ICE Clear Europe's eligibility criteria for gold collateral conforms to certain requirements under the European Market Infrastructure Regulation that gold collateral be held in allocated form.[8]

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[9] For the reasons discussed below, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act[10] and Rule 17Ad–22(e)(5) thereunder.[11]

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICE Clear Europe be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions.[12] Based on its review of the record, and for the reasons discussed below, the Commission believes the proposed changes to the Procedures are consistent with the promotion of the prompt and accurate clearance and settlement of securities transactions.

The Commission believes that accepting gold as Permitted Cover only if in allocated form would help to ensure the availability of that gold for liquidation. Should ICE Clear Europe need to liquidate gold to satisfy a Clearing Member's Initial Margin or Guaranty Fund requirement, the Commission believes gold in allocated form is more likely to be available than gold not in allocated form. The Commission believes this to be the case because allocated gold would be held by a custodian in the name of ICE Clear Europe, giving ICE Clear Europe an interest in specific bars of gold, rather than an interest in shared pool of bars of gold.

The Commission therefore believes that accepting only allocated gold would improve ICE Clear Europe's ability to liquidate that gold if needed, thereby helping to improve ICE Clear Europe's ability to manage potential losses that could result from a Clearing Member's default. The Commission further believes these potential losses, if not properly managed, could disrupt ICE Clear Europe's ability to clear and settle transactions. Accordingly, the Commission believes the proposed rule change, by requiring ICE Clear Europe to only accept allocated gold as Permitted Cover, would be consistent with the promotion of the prompt and accurate clearance and settlement of securities transactions.

Therefore, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[13]

B. Consistency With Rule 17Ad–22(e)(5) Under the Act

Rule 17Ad–22(e)(5) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to, among other things, limit the assets it accepts as collateral to those with low credit, liquidity, and market risks. The Commission believes that accepting gold as Permitted Cover only in allocated form would help to lower the credit risk associated with that gold. As discussed above, allocated gold would give ICE Clear Europe an interest in specific bars of gold, rather than an interest in shared pool of bars of gold. Unallocated gold represents a claim against the custodian for an amount of metal held in bulk, while allocated gold held by a custodian is specifically identified for a particular owner and therefore represents a lower credit risk than unallocated gold. The Commission therefore believes that accepting gold as Permitted Cover only in allocated form would support ICE Clear Europe's ability to limit the assets it accepts as collateral to those with low credit risks.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(5).[14]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act[15] and Rule 17Ad–22(e)(5) thereunder.[16]

It is therefore ordered pursuant to Section 19(b)(2) of the Act[17] that the proposed rule change (SR–ICEEU–2023–013), be, and hereby is, approved.[18]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–16719 Filed 8–4–23; 8:45 am]

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[8] *See* Notice, 88 FR 41440; Commission Delegated Regulation (EU) No 153/2013 of 19 December 2012 supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to regulatory technical standards on requirements for central counterparties, Annex I, Section 3.

[9] 15 U.S.C. 78s(b)(2)(C).

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] 17 CFR 240.17Ad–22(e)(5).

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 15 U.S.C. 78q–1(b)(3)(F).

[14] 17 CFR 240.17Ad–22(e)(5).

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] 17 CFR 240.17Ad–22(e)(5).

[17] 15 U.S.C. 78s(b)(2).

[18] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98038; File No. SR–NYSEARCA–2023–49]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Rule 6.40P–O

August 1, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 27, 2023, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Rule 6.40P–O (Pre-Trade and Activity-Based Risk Controls) to allow certain order types to be excluded from the Activity-Based Risk Controls.

The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 6.40P–O (Pre-Trade and Activity-Based Risk Controls) to allow certain order types to be excluded from the Activity-Based Risk Controls. Specifically, the Exchange proposes to allow OTP Holders and OTP Firms (collectively, ''OTPs'') [3] the ability to exclude orders marked as GTX [4] from counting towards the limits established by the Activity-Based Risk Controls and to exclude GTX orders from cancellation when an Activity-Based Risk Limit is breached.[5]

The Exchange offers OTPs the option of utilizing Activity-Based Risk Controls to assist OTPs in managing risk related to submitting orders during periods of increased and significant trading activity.[6] OTPs acting as Market Makers must apply one of the Activity-Based Risk Controls to all of its orders and quotes, whereas an OTP not acting as a Market Maker may, but is not required to, apply one of the Activity-Based Risk Controls to its orders.[7] To determine when an Activity-Based Risk Control has been breached, the Exchange will maintain a Trade Counter that will be incremented every time an order (or quote) trades, including any leg of a Complex Order, and will aggregate the number of contracts traded during each such execution.[8] When designating one of the three Activity-Based Risk Controls, an OTP must indicate the action that it would like the Exchange to take if an Activity-Based Risk Limit is exceeded.[9] Currently, the Exchange affords OTPs the ability to exclude certain orders from being considered by a Trade Counter.[10] The order types that an OTP may opt to exclude are orders designated as IOC or FOK, which order types are designed to cancel if not executed on arrival.[11] In addition, the Exchange exempts certain orders from being cancelled or blocked—specifically Auction-Only orders (submitted solely for the purpose of being executed in an opening auction) and GTC Orders, which by their terms are meant to eventually execute unless specifically cancelled by the order-sender.[12]

The Exchange proposes to modify Rule 6.40P–O(c)(2)(B) to add GTX to the order types that may be excluded by Trade Counters in tracking Activity-Based Risk Controls.[13] In addition, for OTPs that select the automated breach action of ''Cancel and Block,'' the Exchange proposes to modify Rule 6.40P–O(c)(2)(C)(iii) to provide OTPs the option of instructing the Exchange not to cancel unexecuted GTX orders in the event of a breach.[14]

An order marked GTX, such as an ECO GTX Order, will cancel after executing to the extent possible with a COA Order in a Complex Order Auction.[15] As such, GTX orders are never ranked (as resting interest) in the Consolidated Book. Because GTX orders are submitted for the sole purposes of executing in a COA or cancelling, the Exchange believes providing OTPs the option of exempting these orders from the Activity-Based Risk Controls would enable these OTPs to exclude GTX orders from being counted and avoid potentially triggering their risk settings (prematurely), resulting in the cancellation of open orders. Likewise, the Exchange believes that allowing OTPs to instruct the Exchange not to cancel any unexecuted GTX orders if their risk setting is breached would likewise afford such OTPs additional flexibility. This proposed handling of GTX orders is consistent with how the Exchange currently handles GTX orders per (pre-Pillar) Commentary .01 to Rule 6.40–O (Risk Limitation Mechanism).[16]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] An Options Trading Permit or ''OTP'' is issued by the Exchange for effecting approved securities transactions on the Exchange. *See* Rule 1.1. An ''OTP Holder'' is a natural person, in good standing, who has been issued an OTP and an ''OTP Firm'' is a sole proprietorship, partnership, corporation, limited liability company or other organization in good standing that holds an OTP or upon whom an individual OTP Holder has conferred trading privileges on the Exchange. *See id.* The Exchange notes that an OTP may be acting as a Market Maker, which market participant is subject to heightened requirements. *See, e.g.,* Rule 6.37AP–O(b), (c).

[4] *See supra* note 16 (for description of orders marked as GTX).

[5] *See* proposed Rules 6.40P–O(c)(2)(B) and (c)(2)(C)(iii).

[6] *See* Rule 6.40P–O(a)(3)(A)–(C) (describing the three potential Activity-Based Risk Controls: Transaction-Based Risk Limit; Volume-Based Risk Limit; and Percentage-Based Risk Limit).

[7] *See* Rule 6.40P–O(c)(2)(A).

[8] *See* Rule 6.40P–O(c)(2)(B).

[9] *See* Rule 6.40P–O(c)(2)(C) (describing the potential automated breach actions of Notification Only, Block Only, and Cancel and Block).

[10] *See* Rule 6.40P–O(c)(2)(B).

[11] *See id. See* also Rule 6.62P–O(b)(2) (IOC) and (3) (FOK).

[12] *See* Rule 6.40P–O(c)(2)(C)(iii).

[13] *See* proposed Rule 6.40P–O(c)(2)(B) (providing, in relevant part, that an OTP ''may opt to exclude any orders designated IOC, FOK, or GTX from being considered by a Trade Counter.'')

[14] *See* proposed Rule 6.40P–O(c)(2)(C)(iii) (providing, in relevant part, that an OTP ''may opt to exclude orders designated as GTX from being cancelled.'').

[15] On the Exchange, an OTP may designate an Electronic Complex Order (or ECO) as GTX. *See* Rule 6.91P–O(b)(2). An ''ECO GTX Order'' is an order sent in response to a Complex Order Auction (or COA) and such order is not displayed, must be entered during the Response Time Interval of a COA, must be on the opposite side of the COA Order, and must specify the price, size, and side of the market. Any remaining size of an ECO GTX Order that does not trade with the COA Order will be cancelled at the end of the COA. *See* Rule 6.91P–O(b)(2)(C).

[16] *See* Rule 6.40–O, Commentary .01 (providing, in relevant part, that upon the triggering of an established risk limit, the Exchange would cancel all open orders and quotes in the affected series but

Continued

The Exchange believes that providing OTPs this additional flexibility may encourage more OTPs to utilize the risk settings, which benefits all market participants. The Exchange also believes that the proposed change would result in risk settings that may be better calibrated to suit the needs of certain OTPs (*i.e.,* those that routinely utilize GTX orders) and should encourage OTPs to direct additional order flow and liquidity to the Exchange.

* * * * *

Implementation

The Exchange will announce by Trader Update the implementation date of the proposed rule change, which implementation will be no later than 90 days after the effectiveness of this rule change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[17] in general, and furthers the objectives of Section 6(b)(5) of the Act,[18] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market by providing OTPs greater control and flexibility over setting their risk tolerance, which may enhance the efficacy of the risk settings. Orders marked GTX, including ECO GTX Orders, will cancel after executing to the extent possible with a COA Order as part of a Complex Order Auction. As such, GTX orders are never ranked (as resting interest) in the Consolidated Book. The Exchange believes that certain market participants utilize GTX orders to access liquidity on the Exchange. Thus, the proposed change is designed to accommodate participants that utilize GTX orders in this manner by enabling them to exclude GTX orders from being counted and avoid potentially triggering their risk settings (prematurely), resulting in the cancellation of open orders. In addition, allowing OTPs the option to exclude unexecuted GTX orders from being cancelled in the event of a breach would allow OTPs to utilize this order type without fear of such orders being cancelled before having the opportunity to trade in a Complex Order Auction. As noted herein, this proposed handling of GTX orders (*i.e.,* excluding such orders from cancellation upon triggering of a risk setting) is consistent with how the Exchange currently handles GTX orders per (pre-Pillar) Commentary .01 to Rule 6.40–O (Risk Limitation Mechanism).

The Exchange believes that providing OTPs this additional flexibility may encourage more OTPs to utilize the risk settings, which benefits all market participants. Further, the proposed change would promote just and equitable principles of trade because it would result in risk settings that may be better calibrated to suit the needs of certain OTPs (*i.e.,* those that routinely utilize GTX orders) and should encourage OTPs to direct additional order flow and liquidity to the Exchange. To the extent additional order flow is submitted to the Exchange as a result of the proposed change, all market participants stand to benefit from increased trading. The Exchange notes that an OTP has the option of utilizing risk settings for all orders submitted to the Exchange and, as proposed, would have the additional option of excluding from these risk settings any GTX orders in a given options class submitted to the Exchange.

This proposed change, which was specifically requested by some OTPs, would foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to, and facilitating transactions in, securities as it will be available to all OTPs and may encourage more OTPs to utilize this enhanced functionality to the benefit of all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange is proposing a market enhancement that would provide OTPs with greater control and flexibility over setting their risk tolerance and, potentially, more protection over risk exposure. The proposal is structured to offer the same enhancement to all OTPs and would not impose a competitive burden on any participant. The Exchange does not believe that the proposed enhancement to the existing Activity-Based Risk Controls would impose a burden on competing options exchanges. Rather, the availability of these controls may foster more competition. Specifically, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. When an exchange offers enhanced functionality that distinguishes it from the competition and participants find it useful, it has been the Exchange's experience that competing exchanges will move to adopt similar functionality. Thus, the Exchange believes that this type of competition amongst exchanges is beneficial to the marketplace as a whole as it can result in enhanced processes, functionality, and technologies.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[19] and Rule 19b–4(f)(6) thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6)[21] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–(f)(6)(iii),[22] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The

would exclude from such cancellation any ''orders entered in response to an electronic auction that are valid only for the duration of the auction ('GTX')''.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] 17 CFR 240.19b–4(f)(6).

[22] 17 CFR 240.19b–4(f)(6)(iii).

Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed optional functionality may offer OTPs additional control and flexibility in utilizing the Exchange's Activity-Based Controls and therefore may encourage more OTPs to utilize these risk settings for their orders. Further, the Exchange represents that the proposed handling of GTX orders is consistent with how the Exchange currently handles GTX orders pursuant to Commentary .01 to Rule 6.40–O (Risk Limitation Mechanism).[23] Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[24]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[25] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEARCA–2023–49 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2023–49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2023–49 and should be submitted on or before August 28, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Sherry R. Haywood,

Assistant Secretary.

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[23] *See supra* note 16 and accompanying text.

[24] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78s(b)(2)(B).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98035; File No. SR–IEX–2023–06]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Add a New Fixed Midpoint Peg Order Type

August 1, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 19, 2023, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[3] and Rule 19b–4 thereunder,[4] IEX is filing with the Commission a proposed rule change to add a new fixed midpoint peg order type that pegs to the less aggressive of the order's limit price or the Midpoint Price,[5] but does not re-price based on changes to the NBBO.[6] The Exchange has designated this rule change as ''non-controversial'' under Section 19(b)(3)(A) of the Act[7] and provided the Commission with the notice required by Rule 19b–4(f)(6) thereunder.[8]

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend IEX Rule 11.190 to add a new fixed midpoint peg order type that pegs to the less aggressive of the order's limit price or the Midpoint Price but does not re-price based on changes to the NBBO. As detailed below, a fixed midpoint peg order will cancel back to the User[9] if the NBBO changes such that the resting price of the fixed midpoint peg order is

[3] 15 U.S.C. 78s(b)(1).

[4] 17 CFR 240.19b–4.

[5] *See* IEX Rule 1.160(t).

[6] *See* IEX Rule 1.160(u).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4.

[9] *See* IEX Rule 1.160(qq).

subject to change. In addition, the Exchange proposes four conforming amendments to IEX Rules Rule 11.190(a)(3) and 11.190(h)(3).

Currently, the Exchange offers a midpoint peg order type, which, upon entry and when posting to the Order Book,[10] is automatically adjusted by the System [11] to be equal to and ranked at the less aggressive of the Midpoint Price or the order's limit price.[12] Midpoint peg orders resting on the Order Book are automatically adjusted by the System in response to changes in the midpoint of the NBBO as allowed by the order's limit price, if any.[13] Midpoint peg orders are non-displayed [14] and may have a minimum quantity instruction.[15]

IEX has received informal feedback from Members [16] that they would like the option of having more determinism when submitting midpoint peg orders. Specifically, IEX understands that some Members would like the option of submitting a midpoint peg order that will only execute at the Midpoint Price at the time of entry (or the order's limit price, if less aggressive than the Midpoint Price). These Members note that this functionality would assist with having more determinism of the price at which orders would trade.

Accordingly, IEX proposes to add subparagraph (b)(19) to IEX Rule 11.190, to add the fixed midpoint peg order type. IEX notes that, as proposed, the fixed midpoint peg order is based upon and very similar to IEX's midpoint peg order type, with the following differences: i) a fixed midpoint peg order will cancel if, after the order is booked, the Midpoint Price changes such that the order would need to be re-priced in order to rest at the Midpoint Price or its limit price if less aggressive than the Midpoint Price; ii) a fixed midpoint peg order will cancel if it is received when there is no NBB [17] or NBO,[18] or the NBBO is crossed; iii) a fixed midpoint peg order will not trade while the market is crossed; and iv) a fixed midpoint peg order cannot be submitted with a minimum quantity instruction.[19]

Like a midpoint peg order,[20] the proposed fixed midpoint peg:

- Would upon entry and when posting to the order book, have its price adjusted by the System to be equal to and ranked at the less aggressive of the Midpoint Price or the order's limit price, if any;
- Must be a pegged order;
- May have any TIF described in IEX Rules 11.190(a)(3) and (c);
- Would not be eligible for routing pursuant to IEX Rule 11.230(b) and (c)(2);
- May not be an ISO, as defined in IEX Rule 11.190(b)(12);
- May be submitted with a limit price or without a limit price (an ''unpriced pegged order'');
- Would be eligible to trade only during the Regular Market Session. As provided in IEX Rule 11.190(a)(3)(D), any pegged order marked with a TIF of DAY that is submitted to the System before the opening of the Regular Market Session would be queued by the System until the start of the Regular Market Session; any pegged order that is marked with a TIF other than DAY would be rejected when submitted to the System during the Pre-Market Session. Any pegged order submitted into the System after the closing of the Regular Market Session would be rejected;
- Would not be eligible to display. Pegged orders are always non-displayed;
- May be an odd lot, round lot, or mixed lot; and
- Would be eligible to be invited by the System to Recheck the Order Book to trade against eligible resting contra-side interest as described in IEX Rule 11.230(a)(4)(D).

However, as proposed, a fixed midpoint peg order would differ from a midpoint peg order in the following ways:

- An incoming fixed midpoint peg order would be canceled by the System if it is received when there is no NBB or NBO, or the NBBO is crossed;
- The price of a fixed midpoint peg order would never be re-priced based on changes to the NBBO;
- A fixed midpoint peg order may not have a minimum quantity instruction, as defined in IEX Rule 11.190(b)(11);
- A resting fixed midpoint peg order would be canceled back to the User if any of the following conditions were met:
  - The fixed midpoint peg order to buy (sell) is entered either without a limit price, or with a limit price that is equal to or above (below) the Midpoint Price and is ranked at the Midpoint Price; thereafter, the NBBO changes so that the Midpoint Price changes (''Scenario 1'');
  - The fixed midpoint peg order to buy (sell) is entered at a limit price that is equal to or below (above) the Midpoint Price and is ranked at its limit price; thereafter, the NBBO changes so that the Midpoint Price is lower (higher) than the limit price of the fixed midpoint peg order (''Scenario 2''); or
  - The fixed midpoint peg order to buy (sell) is entered either without a limit price, or with a limit price that is equal to or above (below) the Midpoint Price and is ranked at the Midpoint Price; thereafter the NBBO becomes crossed, such that the Midpoint Price is considered indeterminable as set forth in IEX Rule 11.190(h)(3)(D)(i). However, if the crossing price (NBO for buys/NBB for sells) is equal to the fixed midpoint peg's resting price, the order will not be canceled, but it will be ineligible to trade (''Scenario 3'').

As proposed, IEX would cancel an incoming fixed midpoint peg order that arrives when the market is crossed or there is no NBB or NBO because IEX treats the Midpoint Price as indeterminable [21] during these circumstances and accordingly there is no Midpoint Price for the order to peg to.

As proposed, a fixed midpoint peg order will not re-price after it posts to the Order Book, but would cancel if the Midpoint Price changes such that the resting price of the fixed midpoint peg order is subject to change. The conditions under which a fixed midpoint peg order would cancel that are set forth in Scenarios 1 to 3, above, each represent circumstances in which changed market conditions would cause a midpoint peg to re-price, but (as proposed) would cause a fixed midpoint peg order to cancel, consistent with the purpose of the order type. Specifically, in Scenario 1, the order was booked at the Midpoint Price (either because it had no limit price or a limit price equal to or more aggressive than the Midpoint Price), and the NBBO changes the Midpoint Price. In Scenario 2, the order is booked at a price equal to or less aggressive than the Midpoint Price, and then the market changes such that the new Midpoint Price is less aggressive than the price at which the order had been resting. In Scenario 3, the order is resting at the Midpoint Price and thereafter the NBBO becomes crossed which would trigger a midpoint peg to re-price to the ''crossing price'' (the lowest Protected Offer [22] for buy orders and the highest Protected Bid [23] for sell orders).[24] However, Scenario 3 provides that if the fixed midpoint peg order's resting price is the same as the crossing price, the order would not be canceled or re-priced, but would be ineligible to trade while the market is crossed.

Finally, IEX is proposing to not allow fixed midpoint peg orders to include a minimum quantity instruction (''MQTY'') in order to prevent cancellations inconsistent with the purpose of the fixed midpoint peg order type. IEX's non-displayed price sliding rules are designed to prevent an unprotected displayed odd lot order with that cannot execute with a contra-side order because it does not satisfy that order's MQTY from causing the IEX Order Book to lock or cross. In this circumstance, the System re-prices the

[10] *See* IEX Rule 1.160(p).
[11] *See* IEX Rule 1.160(nn).
[12] *See* IEX Rule 11.190(b)(9).
[13] *See Id.* and IEX Rule 11.190(h)(2).
[14] *See* IEX Rule 11.190(b)(9)(H).
[15] *See* IEX Rules 11.190(b)(9)(G) and (b)(12).
[16] *See* IEX Rule 1.160(s).
[17] *See* IEX Rule 1.160(u).
[18] *See* IEX Rule 1.160(u).
[19] *See* IEX Rule 11.190(b)(11).
[20] *See* IEX Rule 11.190(b)(9).
[21] *See* IEX Rule 11.190(h)(3)(D)(i).
[22] *See* IEX Rule 1.160(bb).
[23] *See* IEX Rule 1.160(bb).
[24] *See* IEX Rule 11.190(h)(3)(D)(i).

resting MQTY order to a price one minimum price variant (''MPV'') [25] less aggressive than the contra-side displayed odd-lot order's price. This functionality could lead a fixed midpoint peg order resting at the Midpoint Price to re-price even if the Midpoint Price has not changed. Accordingly, IEX believes that it is consistent with the purpose of the order type and User expectations to not allow a MQTY instruction to cause a cancellation because the order must re-price despite there being no change to the Midpoint Price.

IEX notes that its proposed fixed midpoint peg order type is substantially similar to the Fixed Midpoint Peg Post-Only Order type offered by Nasdaq PHLX LLC (''Nasdaq PHLX''), with a few minor differences as follows: [26]

- If a Nasdaq PHLX Fixed Midpoint Peg Post-Only Order is submitted with a limit price equal to the Midpoint Price, and the Midpoint Price moves to a more aggressive price than the resting order's limit price, Nasdaq PHLX will not cancel the order. IEX, by contrast, proposes to cancel a fixed midpoint peg order in such circumstances, as set forth in Scenario 2 above. IEX believes that this approach is appropriate because the order type is designed to provide a midpoint execution in a more deterministic manner and in this scenario, the Midpoint Price has changed.
- If the NBBO becomes crossed while a Nasdaq PHLX Fixed Midpoint Peg Post-Only Order is resting on the book Nasdaq PHLX will not cancel the order unless the order would need to be re-priced or an incoming order could match with it.[27] IEX, in contrast will cancel the order as described above if it would otherwise need to be re-priced and if not canceled the order would be ineligible to trade with an incoming order while the NBBO is crossed.[28] These two approaches have the same ultimate effect of preventing trading in a crossed market, and are therefore substantively similar, with the exception that IEX will not necessarily cancel the order to prevent the unwanted trade.
- Nasdaq PHLX permits a Fixed Midpoint Peg Post-Only Order to have a minimum quantity instruction, while IEX proposes to not allow such an instruction. As discussed above, IEX believes that not allowing a minimum quantity instruction is more consistent with the purpose of the order type and User expectations.

In addition, the Exchange proposes four conforming amendments to other IEX rules:

- Amend IEX Rule 11.190(a)(3) to add fixed midpoint peg orders to the list of pegged order types offered by IEX;
- Amend IEX Rule 11.190(a)(3) to add fixed midpoint peg to the list of orders that may execute in sub-pennies if necessary to obtain a Midpoint Price;
- Amend IEX Rule 11.190(h)(3)(D)(i) to add a sentence at the end stating that in a crossed market, ''fixed midpoint peg orders will be canceled back to the User unless the crossing price is equal to the fixed midpoint peg order's resting price.'' This sentence reflects the fixed midpoint peg order functionality in proposed IEX Rule 11.190(b)(19). IEX notes that this functionality is consistent with the manner in which it will cancel an incoming fixed midpoint peg order during a crossed market, and is identical to how Nasdaq PHLX handles Fixed Midpoint Peg Post-Only Orders in a crossed market; [29] and
- Amend IEX Rule 11.190(h)(3)(D)(iii) to add fixed midpoint peg to the list of orders that are not eligible to trade when the market is crossed in IEX Rule 11.190(h)(3)(D)(iii). This functionality is also identical to how Nasdaq PHLX prevents Fixed Midpoint Peg Post-Only Orders from trading in a crossed market.[30]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[31] in general, and furthers the objectives of Section 6(b)(5),[32] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that the proposed rule change is consistent with the protection of investors and the public interest because it is designed to provide an optional order type for Users seeking a midpoint execution in a more deterministic manner, as described in the Purpose section.

Further, IEX believes that the proposal is consistent with the protection of investors and the public interest in that the fixed midpoint peg order type would provide additional flexibility to market participants in their use of pegging orders. As described in the Purpose section, the fixed midpoint peg order would provide market participants with more control over the price at which their midpoint pegging orders execute because the order's price would not move with changes to the Midpoint Price. IEX understands that such functionality could be useful for execution strategies designed to avoid chasing rising quotes or ones predicated on greater precision of execution prices. IEX believes that implementing this functionality through an exchange order type will make it more widely available to market participants on a fair and non-discriminatory basis.

Furthermore, IEX believes that its proposed treatment of fixed midpoint peg orders during crossed market is consistent with the Act because the Midpoint Price is indeterminable during a crossed market so trading during such time would be inconsistent with the purpose of the order type.

Additionally, IEX believes that the proposal to not allow a fixed midpoint peg order to have a MQTY instruction is consistent with the protection of investors and the public interest in that this functionality is designed to prevent inconsistent cancellations if the MQTY instruction prevented a fixed midpoint peg order from executing and instead caused the System to re-price the order. As discussed in the Purpose section, because these orders are designed to cancel rather than re-price, IEX believes that it is consistent with the purpose of the order type and User expectations to not allow a MQTY instruction.

The Exchange also believes that the proposed rule change is consistent with the protection of investors and the public interest because it is designed to increase competition among execution venues by providing market participants with additional options and flexibility in their use of pegging orders, as described in the Purpose section, and thereby enable the Exchange to better compete with other trading venues that offer similar features to market participants.

Finally, as noted in the Purpose section, this proposal is substantially similar to Nasdaq PHLX's Fixed Midpoint Peg Post-Only Order type, with three minor differences in implementation as discussed in the Purpose section.[33] As discussed in the Purpose section, IEX believes that its proposed approach to each of these minor differences is consistent with the purpose of the fixed midpoint peg order type and Users' expectations. Thus, IEX does not believe that the proposed changes raise any new or novel material issues that have not already been considered by the Commission, notwithstanding these minor differences.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not

[25] *See* IEX Rule 11.210.

[26] *See* Nasdaq PHLX Rule 3301A(b)(6).

[27] *See supra* note 27.

[28] *See* proposed IEX Rule 11.190(h)(3)(D)(iii).

[29] *See supra* note 27.

[30] *See supra* note 27.

[31] 15 U.S.C. 78f(b).

[32] 15 U.S.C. 78f(b)(5).

[33] *See supra* note 27.

necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the proposal is a competitive response to similar order types available on other exchanges.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Competing exchanges have and can continue to adopt similar order types, subject to the SEC rule change process, as discussed in the Purpose and section.

The Exchange also does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. All Members would be eligible to use the fixed midpoint peg order type on the same terms.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [34] and Rule 19b–4(f)(6) thereunder.[35] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [36] and Rule 19b–4(f)(6) thereunder.[37]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–IEX–2023–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–IEX–2023–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions. You should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–IEX–2023–06 and should be submitted on or before August 28, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–16710 Filed 8–4–23; 8:45 am]

BILLING CODE 8011–01–P

[34] 15 U.S.C. 78s(b)(3)(A).

[35] 17 CFR 240.19b–4(f)(6).

[36] 15 U.S.C. 78s(b)(3)(A).

[37] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[38] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Meeting of the Interagency Task Force on Veterans Small Business Development

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the date, time, and agenda for the next meeting of the Interagency Task Force on Veterans Small Business Development (IATF).

DATES: Wednesday, September 13, 2023, from 1 p.m. to 3 p.m. ET.

ADDRESSES: The meeting will be held virtually via Microsoft Teams.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is strongly encouraged. To RSVP and confirm attendance, the public should email *veteransbusiness@sba.gov* with subject line, ''RSVP for September 13, 2023, IATF Public Meeting.'' To submit a written comment, individuals should email *veteransbusiness@sba.gov* with subject line, ''Response for September 13, 2023, IATF Public Meeting'' no later than September 8, 2023, or contact Timothy Green, Acting Associate Administrator, Office of Veterans Business Development (OVBD) at (202) 205–6773. Comments received in advanced will be addressed as time allows during the public comment period. All other submitted comments will be included in the meeting record. During the live meeting, those who wish to comment will be able to do so during the public comment period. Participants can join the meeting via computer at this link: *https://bit.ly/IATF-Sept2023* or by phone. Call in (audio only): Dial: +1 206–413–7980: Phone Conference ID: 682 293 143#. Special accommodation requests should be directed to OVBD at (202) 205–6773 or *veteransbusiness@sba.gov.* All applicable documents will be posted on the IATF website prior to the meeting: *https://www.sba.gov/about-sba/sba-locations/headquarters-offices/office-veterans-business-development#sba-card-collection--heading-7381.* For more information on

veteran-owned small business programs, please visit *www.sba.gov/ovbd.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development (IAFT). The IATF is established pursuant to Executive Order 13540 to coordinate the efforts of Federal agencies to improve capital, business development opportunities, and pre-established Federal contracting goals for small business concerns owned and controlled by veterans and service-disabled veterans. The purpose of this meeting is to discuss efforts that support veteran-owned small businesses, updates on past and current events, and the IATF's objectives for fiscal year 2023.

Dated: August 1, 2023.

Andrienne Johnson,

Committee Manager Officer.

[FR Doc. 2023–16735 Filed 8–4–23; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

Meeting of the Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the date, time, and agenda for a meeting of the Advisory Committee on Veterans Business Affairs (ACVBA).

DATES: Thursday, September 14, 2023, from 9:00 a.m. to 1:00 p.m. ET.

ADDRESSES: The meeting will be held via Microsoft Teams using a call-in number listed below.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is strongly encouraged. To RSVP and confirm attendance, the general public should email *veteransbusiness@sba.gov* with subject line, ''RSVP for September 14, 2023, ACVBA Public Meeting.'' To submit a written comment, individuals should email *veteransbusiness@sba.gov* with subject line, ''Response for September 14, 2023, ACVBA Public Meeting'' no later than September 8, 2023, or contact Timothy Green, Acting Associate Administrator, Office of Veterans Business Development (OVBD) at (202) 205–6773. Comments received in advanced will be addressed as time allows during the public comment period. All other submitted comments will be included in the meeting record. During the live meeting, those who wish to comment will be able to do so during the public comment period.

Participants can join the meeting via computer *https://bit.ly/ACVBA-Sept2023* or by phone. Call in (audio only): Dial: +1 206–413–7980: Phone Conference 236 187 565#. Special accommodation requests should be directed to OVBD at (202) 205–6773 or *veteransbusiness@sba.gov.* All applicable documents will be posted on the ACVBA website prior to the meeting: *https://www.sba.gov/about-sba/sba-locations/headquarters-offices/office-veterans-business-development#sba-card-collection--heading-7381.* For more information on veteran-owned small business programs, please visit *www.sba.gov/ovbd.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs. The ACVBA is established pursuant to 15 U.S.C. 657(b) note and serves as an independent source of advice and policy. The purpose of this meeting is to discuss efforts that support veteran-owned small businesses, updates on past and current events, and the ACVBA's objectives for fiscal year 2023.

Dated: August 1, 2023.

Andrienne Johnson,

Committee Manager Officer.

[FR Doc. 2023–16737 Filed 8–4–23; 8:45 am]

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SURFACE TRANSPORTATION BOARD

60-Day Notice of Intent To Seek Extension of Approval of Collection: Statutory Licensing Authority

AGENCY: Surface Transportation Board.

ACTION: Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an extension of approval for the information collection required from those seeking statutory licensing authority, as described below.

DATES: Comments on this information collection should be submitted by October 6, 2023.

ADDRESSES: Direct all comments to Chris Oehrle, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001, or to *PRA@stb.gov.* When submitting comments, please refer to ''Paperwork Reduction Act Comments, Statutory Licensing Authority.'' For further information regarding this collection, contact Michael Higgins, Deputy Director, Office of Public Assistance, Governmental Affairs, and Compliance, at (202) 245–0284 or at *Michael.Higgins@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Comments are requested concerning: (1) the accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Description of Collection

Title: Statutory Licensing Authority.

OMB Control Number: 2140–0023.

STB Form Number: None.

Type of Review: Extension without change.

Respondents: Rail carriers and non-carriers seeking statutory licensing or consolidation authority, an exemption from filing an application for such authority, or interchange commitments.

Number of Respondents: 85.

Estimated Time per Response:

ESTIMATED HOURS PER RESPONSE

Type of filing	Number of hours per response under 49 U.S.C. 10901–03 and 11323–26
Applications	575
Petitions *	75
Notices *	25
Interchange commitments	10

* Under section 10502, petitions for exemption and notices of exemption are permitted in lieu of an application.

Frequency: On occasion.

AVERAGE ANNUAL NUMBER OF RESPONSES FOR FY 2020–2022

Type of filing	Average number of filings per year under 49 U.S.C. 10901–03 and 11323–26
Applications	7
Petitions *	15
Notices *	88
Interchange commitments	5

* Under section 10502, petitions for exemption and notices of exemption are permitted in lieu of an application.

Total Burden Hours (annually including all respondents): 7,300 hours (sum of estimated hours per response × number of responses for each type of filing).

TOTAL ANNUAL BURDEN HOURS

Type of filing	Hours per response	Annual number of filings	Total annual burden hours
Applications	575	7	4,025
Petitions *	75	15	1,125
Notices *	25	88	2,200
Interchange commitments	10	5	50
Total annual burden hours	.....	.....	7,300

* Under section 10502, petitions for exemption and notices of exemption are permitted in lieu of an application.

Total ''Non-hour Burden'' Cost: None identified. Filings are submitted electronically to the Board.

Needs and Uses: As mandated by Congress, an application for prior approval and authority must be filed with the Board by persons seeking to construct, acquire, or operate a line of railroad; by railroads seeking to abandon or discontinue operations over a line of railroad; and, in the case of two or more railroads, by railroads seeking to consolidate their interests through merger or a common-control arrangement. *See* 49 U.S.C. 10901–03, 11323–26. Under 49 U.S.C. 10502, persons may seek an exemption from many of the application requirements of sections 10901–03 and 11323–26 by filing with the Board a petition for exemption or notice of exemption in lieu of an application. The collection by the Board of these applications, petitions, and notices (including collection of disclosures of rail ''interchange commitments'' under 49 CFR 1121.3(d), 1150.33(h), 1150.43(h), and 1180.4(g)(4)) enables the Board to meet its statutory duty to regulate the referenced rail transactions. If the actions for which authority is sought create agreements with interchange commitments that limit the future interchange of traffic with third parties, then certain information must be disclosed to the Board about those commitments. 49 CFR 1121.3(d), 1150.33(h), 1150.43(h), 1180.4(g)(4). The collection of this information facilitates the case-specific review of interchange commitments and enables the Board's monitoring of their usage generally.

Under the PRA, a federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Under 44 U.S.C. 3506(c)(2)(A), federal agencies are required to provide, prior to an agency's submitting a collection to OMB for approval, a 60-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: August 2, 2023.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2023–16810 Filed 8–4–23; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

60-Day Notice of Intent To Seek Extension of Approval of Collection: Household Goods Movers' Disclosure Requirements

AGENCY: Surface Transportation Board.

ACTION: Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an extension of the information collection (here, third-party disclosures), as described below.

DATES: Comments on this information collection should be submitted by October 6, 2023.

ADDRESSES: Direct all comments to Chris Oehrle, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001, or to *PRA@stb.gov.* When submitting comments, please refer to ''Paperwork Reduction Act Comments, Surface Transportation Board: Household Goods Movers' Disclosure Requirements.'' For further information regarding this collection, contact Michael Higgins, Deputy Director, Office of Public Assistance, Governmental Affairs, and Compliance, at (202) 245–0284 or *michael.higgins@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Comments are requested concerning: (1) the accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology when

appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Description of Collection

Title: Household Goods Movers' Disclosure Requirements.

OMB Control Number: 2140–0027.

STB Form Number: None.

Type of Review: Extension without change.

Respondents: Household goods movers (HHG Movers) that desire to offer a rate limiting their liability on interstate moves to anything less than replacement value of the goods.

Number of Respondents: 5,273 (approximate number of active household goods carriers in the United States according to the Federal Motor Carrier Safety Administration (FMCSA)). *See* 2022 Pocket Guide to Large Truck and Bus Statistics (December 2022) section 1–7 Household Goods Carriers and Brokers Operating in the United States, 2017–2021.

Frequency: On occasion.

Total Burden Hours: 101 hours. Household goods movers provide prospective clients with a prescribed form estimating the charges for the anticipated move and providing various warnings and disclosures, including a disclosure of the availability of two levels of recovery for loss and damage incurred during the move. The Board's request for approval of the initial estimate form contained a cost analysis indicating that inclusion of the loss-and-damage information was a one-time, start-up cost, and that an estimated 15 of the thousands of HHG Movers were large firms that print their own forms and that had already produced modified forms to meet the new requirement. The original request for approval also indicated that only a relatively small number of new entrants would have to create the required notice forms each year. Using 2022 Pocket Guide to Large Truck and Bus Statistics (section 1–7) to determine the latest three-year increase in the number of HHG Movers, Board staff estimates that there are approximately 202 of these new carriers that have entered the business annually over the last three reported years. Each of these new entrants would require approximately one hour to review the released rate decision and to cut and paste the warnings/disclosures into a general electronic form, but only a portion of that time (about half) would be allotted to the Board's released rate disclosure requirement. Therefore, the Board estimates that the annual hourly burden for this collection is 101 hours per year for the industry (202 responses annually × ½ × 1 hour = 101 burden hours).

Total ''Non-Hour Burden'' Cost: HHG Movers may provide these forms to shippers electronically.

Needs and Uses: In the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, section 4215, Public Law 109–59, 119 Stat. 1144, 1760 (2005), Congress directed the Board to review consumer protection regulations concerning the loss or damage to property that occurs during interstate household goods moves. In Docket No. RR 999, the Board required household goods motor carriers and freight forwarders wishing to offer a rate limiting their liability on interstate moves to anything less than replacement value of the goods to provide their customers with clear written information concerning the two available cargo-liability options (a full replacement-value protection option and a lower, released-rate protection option). HHG Movers are required to provide this information on the standard written estimate form that the FMCSA requires HHG Movers to provide to their household goods moving customers. *See* 49 CFR 375.213. This information allows for early notice to household goods moving customers regarding the two liability options, as well as adequate time and information to help consumers decide which option to choose. If the customer elects anything other than full-value protection, the HHG Mover must inform the customer of their rights and obtain a signed waiver, as provided on the form. In doing so, this collection enables the Board to meet its statutory duty.

Under the PRA, a Federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Under 44 U.S.C. 3506(c)(2)(A), Federal agencies are required to provide, prior to an agency's submitting a collection to OMB for approval, a 60-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: August 2, 2023.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2023–16809 Filed 8–4–23; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–1169]

Agency Information Collection Activities: Requests for Comments; Clearance of a New Approval of Information Collection: Inflation Reduction Act Fueling Aviation's Sustainable Transition Grant Program

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for a new information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 24, 2023. The collection involves soliciting project proposals for the Inflation Reduction Act (IRA) Fueling Aviation's Sustainable Transition (FAST) Grant Program. The information to be collected will be used to determine projects to be awarded FAST competitive discretionary grants.

DATES: Written comments should be submitted by September 6, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Chris Dorbian by email at: *christopher.dorbian@faa.gov;* phone: 202–267–8156.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d)

ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–XXXX.

Title: Inflation Reduction Act Fueling Aviation's Sustainable Transition Grant Program.

Form Numbers: OMB Number 4040–0004, 4040–0006, 4040–0007, 4040–0008, 4040–0009, 4040–0010.

Type of Review: New information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 24, 2023 (88 FR 33659). The FAA is using this collection to solicit the information necessary to evaluate and select sustainable aviation fuel and low-emission aviation technology projects for funding under the Inflation Reduction Act (IRA), signed on August 16, 2022. Section 40007 of the Inflation Reduction Act of 2022 directs the Secretary of Transportation to implement a ''competitive grant program for eligible entities to carry out projects located in the United States that produce, transport, blend, or store sustainable aviation fuel, or develop, demonstrate, or apply low-emission aviation technologies.'' The Department of Transportation (DOT), Federal Aviation Administration (FAA) is seeking to establish this new grant program—named the Fueling Aviation's Sustainable Transition (FAST) Grant Program—and collect project proposals via a Notice of Funding Opportunity (NOFO). FAST will have elements focused on sustainable aviation fuel (SAF), to be termed FAST–SAF, and elements focused on low-emission aviation technologies, to be termed FAST-Tech. The program aims to reduce the greenhouse gas emissions (GHG) associated with the aviation sector, in line with the net-zero GHG by 2050 goal outlined in the U.S. Aviation Climate Action Plan. The amount of available funding for the two programs is $244.53M and $46.53M for FAST–SAF and FAST-Tech, respectively.

The NOFO will solicit project proposals from eligible entities. The collected information is required for FAA to evaluate proposals and distribute IRA funds to address U.S. climate goals. Eligible entities who elect to compete for funding and obtain benefits from the FAST Grant Program will submit project information. The information collected is based on grant criteria outlined in the IRA Section 40007.

The FAA will use information submitted to evaluate and select projects for funding that most closely align with the criteria outlined in the NOFO. A team of subject matter experts in aircraft technology development and sustainable aviation fuels from the FAA and other government agencies will assess each application against the applicable criteria. The information FAA is collecting will include technical, project management, and cost proposals for candidate projects. Key evaluation criteria include the capacity for the project to increase the domestic production and deployment of SAF or the use of low-emission aviation technologies and the projected greenhouse gas emissions from such a project.

Project information will be solicited through a NOFO published to *grants.gov.* Applications will be collected via *grants.gov.* The NOFO will outline in detail the form of the full application.

Respondents: Eligible entities as outlined in IRA Section 40007.

Frequency: One-time application per phase of funding.

Estimated Average Burden per Response: Approximately 500 hours.

Estimated Total Annual Burden: Approximately 25,000 hours (assuming 50 applicants).

Issued in Washington, DC, on August 2, 2023.

Julie Marks,

Executive Director (Acting), Federal Aviation Administration—Office of Environment and Energy.

[FR Doc. 2023–16805 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–1480]

Agency Information Collection Activities: Requests for Comments; Clearance of Continued Approval of Information Collection: Limited Recreational Unmanned Aircraft Operation Applications

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request Office of Management and Budget (OMB) approval to continue information collection. The collection involves information related to recreational flying under the Exception for Limited Recreational Operations of Unmanned Aircraft. The information collected will be used to recognize Community Based Organizations (CBOs), administer an aeronautical knowledge and safety test, establish fixed flying sites, approve standards and limitations for Unmanned Aircraft Systems (UAS) weighing more than 55 pounds, and designate FAA Recognized Identification Areas (FRIAs).

DATES: Written comments should be submitted by October 6, 2023.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Alvin A Brunner, AFS–830/SPS, 800 Independence Ave. SW, Washington, DC 20591.

By email: alvin.a.brunner@faa.gov.

FOR FURTHER INFORMATION CONTACT: Alvin Brunner by email at: *alvin.a.brunner@faa.gov;* phone: (405) 666–1024.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0794.

Title: Limited Recreational Unmanned Aircraft Operation Applications.

Form Numbers: Online collection.

Type of Review: Continued information collection.

Background: In 2018, Congress passed the FAA Reauthorization Act of 2018 (Pub. L. 115–254). Section 44809 of Public Law 115–254 allows a person to operate a small unmanned aircraft (UA) without specific certification or operating authority from the FAA if the operation adheres to certain limitations. These limitations require the FAA to recognize community-based organizations (CBOs), develop and administer an aeronautical knowledge and safety test, establish fixed flying sites, approve standards and limitations for unmanned aircraft weighing more than 55 pounds, and designate FAA Recognized Identification Areas (FRIAs).

The information will be collected online, primarily through the FAA's DroneZone website. The information

collected will be limited to only that necessary for the FAA to complete a review of an application under the following statutory requirements:

- Section 44809(c)(1), Operations at Fixed Sites
- Section 44809(c)(2)(a), Standards and Limitations—UA Weighing More Than 55 Pounds
- Section 44809(c)(2)(b), Operations at Fixed Sites—UA Weighing More Than 55 Pounds
- Section 44809(g)(1), Aeronautical Knowledge and Safety Test
- Section 44809(i), Recognition of Community-Based Organizations

Respondents: Individuals and organizations operating under the Exception for Limited Recreational Operations of Unmanned Aircraft who wish to be recognized as CBOs, administer the aeronautical knowledge and safety test, establish fixed flying sites, have standards and limitations for unmanned aircraft weighing more than 55 pounds approved, and establish designated FRIAs.

Frequency: On occasion.

Estimated Average Burden per Response: Varies depending on the type of stakeholder application. Fixed flying site applications (including more than 55 pound UAS and FRIA) are estimated to take 0.5 hours per applicant. CBO recognition and more than 55 pound UAS standards and limitations applications are estimated to take 1.0 hours per applicant.

Estimated Total Annual Burden: Varies depending on the type of stakeholder application. CBO recognition and more than 55 pound UAS standards and limitations applications are not recurring, resulting in a one-time annual burden of 1 hour per application. However, this number can vary greatly as incomplete applications are quickly denied, but complete application that include over 55 pound UAS can take two or more hours. Fixed flying site applications are required to be updated/renewed annually, resulting in a total annual burden of 0.5 hours per year.

The FAA estimates 25 CBO recognition/more than 55 pound UAS standards and limitations applications in the first year, totaling 25 hours. Fixed flying site applications (including more than 55 pound UAS and FRIA) are expected to number around 200 applications per year, totaling 100 hours.

Issued in Washington, DC, on August 2, 2023.

D.C. Morris,

Aviation Safety Analyst, Flight Standards Service, General Aviation and Commercial Division.

[FR Doc. 2023–16852 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–0976]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: National Air Tours Safety Standards

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 1, 2023. The collection involves requirements in FAA regulations that set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tours to submit information.

DATES: Written comments should be submitted by September 6, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sandra Ray by email at: *Sandra.ray@faa.gov;* phone: 412–546–7344

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0717.

Title: National Air Tours Safety Standards.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 1, 2023 (88 FR 26640). FAA regulations set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tour operators to submit information. The FAA uses the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, take enforcement action on violators of the regulations.

Respondents: Commercial Air Tour Operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: Varies by response.

Estimated Total Annual Burden: 1,400 Hours.

Issued in Washington, DC, on August 2, 2023.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2023–16769 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0480]

Commercial Driver's License Standards: Application for Exemption Renewal; CRST The Transportation Solution (Formerly Known as CRST Expedited, Inc.)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of exemption renewal; request for comments.

SUMMARY: FMCSA announces its decision to provisionally renew the exemption currently held by CRST The Transportation Solution (CRST) (formerly known as CRST Expedited, Inc.) from the requirement that a commercial driver's license (CDL) holder with the proper CDL class and endorsements be seated in the front seat

of the commercial motor vehicle (CMV) at all times while the commercial learner's permit (CLP) holder is engaged in behind-the-wheel training on public roads or highways. Under the terms and conditions of the exemption, a CLP holder who has passed the skills test but not yet received the CDL document may drive a CRST CMV accompanied by a CDL holder who is not necessarily in the passenger seat, provided the CLP driver possesses documentation of passing from the State that administered the skills test. The exemption renewal is for five years.

DATES: This renewed exemption is effective September 24, 2023, and expires on September 24, 2028. Comments must be received on or before September 6, 2023.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2015–0480 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number for this notice (FMCSA–2015–0480). Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, 20590–0001 between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption renewal request. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Mrs. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4225; Email: *pearlie.robinson@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2015–0480), indicate the specific section of this document to which the comment applies and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number FMCSA–2015–0480 in the ''Search'' box, and click ''Search.'' When the new screen appears, click on ''Documents'' button, then click the ''Comment'' button associated with the latest notice posted. Another screen will appear; insert the required information. Choose whether you are submitting your comment as an individual, an organization, or anonymous. Click ''Submit Comment.''

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b)(2) and 49 CFR 381.300(b) to renew an exemption from the Federal Motor Carrier Safety Regulations for a 5-year period if it finds that ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' CRST has requested a five-year extension of the current exemption in Docket No. FMCSA–2015–0480.

III. Background

Current Regulation(s) Requirements

FMCSA's CDL regulations in 49 CFR 383.25 establish minimum requirements for the CLP to be considered a valid CDL during behind-the-wheel training of a CLP holder on public roads or highways. Section 383.25(a)(1) requires a CDL holder with the proper CDL class and endorsements necessary to operate the CMV to accompany a CLP holder and be physically present in the front seat of the CMV next to the CLP holder at all times or, in a commercial passenger vehicle, directly behind or in the front row behind the driver, and must have the CLP holder under observation and direct supervision.

Application for Renewal of Exemption

Background

On September 23, 2016, FMCSA granted CRST a five-year exemption from 49 CFR 383.25(a)(1) because CLP holders who have passed the CDL skills test are professionally qualified and eligible to obtain a CDL, which indicates that CRST would likely achieve a level of safety equivalent to or greater than the level of safety obtained by complying with the regulation (81 FR 65696). On October 19, 2018, CRST requested renewal of its original exemption. FMCSA granted the request for renewal for an additional five-year period. The renewed exemption expires on September 24, 2023.

CRST has requested an additional five-year renewal of the exemption. CRST believes that FMCSA should renew the exemption because it results in safer drivers. CRST noted that:

> As it respects CRST's CLP holders, these drivers have already successfully passed all required CDL skills testing, and related prerequisites, required to lawfully take receipt of the CDL. What remains for CRST CLP holders is to travel to the DMV [Department of Motor Vehicles] in their respective home state to obtain physical receipt of their CDL. The only difference between a CRST CLP holder who has passed their skills testing via a registered ELDT training provider with the documentation of successful skills testing results in the Commercial Skills Test Information Management System (CSTIMS), and other newly credentialed CDL drivers is the physical possession of the CDL document.

CRST estimates that approximately 1,000 new drivers per year will operate

a CMV under the exemption, if the renewal is granted. It states that allowing the CLP drivers to operate under the exemption would not result in a degradation of safety because ''there is no material difference between the skill of a new driver that has passed the required skills testing as part of their entry-level driver training and a new driver that has just received their DMV-issued CDL document.'' CRST assesses that the exemption will improve safety because new CDL holders are allowed to drive unsupervised immediately after receiving their documentation whereas CLP drivers operating under this exemption will be accompanied by an experienced CDL holder providing some guidance.

A copy of CRST's request has been placed in the docket to this notice.

IV. Equivalent Level of Safety

FMCSA determined in 2016 and again in 2018 that CRST drivers would likely achieve a level of safety equivalent to, or greater than, the level of safety achieved without the exemption. FMCSA noted in its October 19, 2018, notice that because these drivers have already met all the requirements for a CDL, but have yet to pick up the CDL document from their State of domicile, their safety performance is expected to be the same as any other newly credentialed CDL holder. Additionally, having a CDL driver accompany the CLP driver who has successfully passed all required CDL skills testing and prerequisites, provides some additional supervision that is otherwise not required for newly credentialed CDL drivers in physical possession of the CDL document.

FMCSA is unaware of any evidence of a degradation of safety attributable to the current exemption for CRST drivers. There is no indication of an adverse impact on safety while CRST drivers have been operating under the terms and conditions specified in the initial exemption or 2018 exemption renewal.

FMCSA therefore concludes that provisionally renewing the exemption granted on October 19, 2018, for another five years, under the terms and conditions listed below, will likely achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

V. Exemption Decision

A. Grant of Exemption

FMCSA provisionally renews the exemption for a period of five years subject to the terms and conditions of this decision and the absence of adverse public comments that would cause the Agency to terminate the exemption. The exemption from the requirements of 49 CFR 383.25(a)(1), is otherwise effective September 24, 2023, through September 23, 2028, 11:59 p.m. local time, unless renewed or revoked.

B. Applicability of Exemption

The exemption relieves CRST from the requirement that a driver accompanying a CLP holder be physically present in the front seat of a CMV on the condition that the CLP holder (i) has successfully passed a CDL skills test administered by the testing State and (ii) possesses supporting documentation from that State.

C. Terms and Conditions

When operating under this exemption, CRST and its drivers are subject to the following terms and conditions:

(1) CRST and its drivers must comply with all other applicable Federal Motor Carrier Safety Regulations (49 CFR parts 350–399);

(2) The drivers must be in possession of a valid State driver's license, a CLP with the required endorsements, and documentation from the testing State that they have passed the CDL skills test;

(3) The drivers must not be subject to any out-of-service order or suspension of driving privileges; and

(4) The drivers must be able to provide this exemption document to enforcement officials.

D. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

E. Notification to FMCSA

CRST must notify FMCSA within 5 business days of any accident (as defined in 49 CFR 390.5) involving any of its CMVs operating under the terms of this exemption. The notification must include the following information:

(a) Name of the exemption: ''CRST''.

(b) Date of the accident.

(c) City or town, and State, in which the accident occurred, or closest to the accident scene.

(d) Driver's name and license number.

(e) Vehicle number and State license number.

(f) Number of individuals suffering physical injury.

(g) Number of fatalities.

(h) The police-reported cause of the accident.

(i) Whether the driver was cited for violation of any traffic laws, motor carrier safety regulations.

(j) The driver's total driving time and total on-duty time prior to the accident.

Reports filed under this provision shall be emailed to *MCPSD@DOT.GOV*.

F. Termination

FMCSA does not believe the drivers covered by this exemption will experience any deterioration of their safety record. The exemption will be rescinded if: (1) CRST and drivers operating under the exemption fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objects of 49 U.S.C. 31136(e) and 31315(b). FMCSA further reserves the right to terminate this exemption in the event it is no longer necessary due to revised regulatory requirements.

VI. Request for Comments

FMCSA requests public comment from all interested persons on CRST's application for a renewal of the exemption. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption.

Robin Hutcheson,

Administrator.

[FR Doc. 2023–16850 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0162]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ELLAKAI (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry

no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0162 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0162 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0162, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ELLAKAI is:

—*Intended Commercial Use of Vessel:* ''The vessel is intended to be used as a charter vessel for commercial hire to carry passengers for tours and fishing.''

—*Geographic Region Including Base of Operations:* ''Alaska'' (Base of Operations: Juneau, AK)

—*Vessel Length and Type:* 28′7″

The complete application is available for review identified in the DOT docket as MARAD 2023–0162 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0162 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16828 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0164]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: BLUE LAGOON (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief

description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0164 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0164 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0164, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel BLUE LAGOON is:

—*Intended Commercial Use of Vessel:* ''Charters in Galveston Bay''
—*Geographic Region Including Base of Operations:* ''Texas'' (Base of Operations: Hitchcock, TX)
—*Vessel Length and Type:* 43′ Catamaran

The complete application is available for review identified in the DOT docket as MARAD 2023–0164 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0164 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16827 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0168]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: STONE CRAB (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0168 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0168 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0168, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel STONE CRAB is:

—*Intended Commercial Use of Vessel:* ''Miami Boat History Tours.''

—*Geographic Region Including Base of Operations:* ''Florida.'' (Base of Operations: Miami, FL)

—*Vessel Length and Type:* 36′ Trawler

The complete application is available for review identified in the DOT docket as MARAD 2023–0168 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0168 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16836 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0158]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SOUND CHOICE (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0158 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0158 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0158, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include

your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel SOUND CHOICE is:

—*Intended Commercial Use of Vessel:* ''Hunting, Fishing & Transport Services. Coastguard Coastwise''
—*Geographic Region Including Base of Operations:* ''Alaska'' (Base of Operations: Kodiak, AK)
—*Vessel Length and Type:* 54′5″ Motor Yacht

The complete application is available for review identified in the DOT docket as MARAD 2023–0158 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0158 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16835 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0156]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: WILD FIG (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0156 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0156 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0156, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel WILD FIG is:

—*Intended Commercial Use of Vessel:* ''Light Day Charters.''
—*Geographic Region Including Base of Operations:* ''Massachusetts, Rhode Island, Florida.'' (Base of Operations: Nantucket, MA)
—*Vessel Length and Type:* 44′ Sport Cruiser

The complete application is available for review identified in the DOT docket as MARAD 2023–0156 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0156 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16837 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0160]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: HANNA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0160 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0160 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0160, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in

nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel HANNA is:

—*Intended Commercial Use of Vessel:* ''Charter Vessel''
—*Geographic Region Including Base of Operations:* ''Rhode Island, Florida.'' (Base of Operations: Newport, RI)
—*Vessel Length and Type:* 80′ 7″ Motor Yacht

The complete application is available for review identified in the DOT docket as MARAD 2023–0160 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0160 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16830 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0159]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MAKAI (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0159 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0159 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0159, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the

intended service of the vessel MAKAI is:

—*Intended Commercial Use of Vessel:* ''The vessel will be used for captained sailing tours of the San Juan Islands''

—*Geographic Region Including Base of Operations:* ''Washington, Oregon'' (Base of Operations: Gig Harbor, WA)

—*Vessel Length and Type:* 33′ 8″ Sail

The complete application is available for review identified in the DOT docket as MARAD 2023–0159 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2023–0159 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16832 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0167]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: HOOKED HER (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0167 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0167 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0167 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel HOOKED HER is:

—*Intended Commercial Use of Vessel:* ''Charter.''

—*Geographic Region Including Base of Operations:* ''Florida.'' (Base of Operations: Palm Beach Gardens, FL)

—*Vessel Length and Type*: 73′6″ Motor

The complete application is available for review identified in the DOT docket

as MARAD 2023–0167 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0167 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16838 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0161]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: KITCHEN PASS III (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0161 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0161 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0161, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel KITCHEN PASS III is:

—*Intended Commercial Use of Vessel:* ''Sport Fishing—Charter Fishing for hire''

—*Geographic Region Including Base of Operations:* ''Wisconsin'' (Base of Operations: Port Washington, WI)

—*Vessel Length and Type:* 40′ motor

The complete application is available for review identified in the DOT docket as MARAD 2023–0161 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or

a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0161 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16831 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0157]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MALOLO (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0157 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0157 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0157, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MALOLO is:

—*Intended Commercial Use of Vessel:* ''Private Vessel Charters, Passengers Only''

—*Geographic Region Including Base of Operations:* ''Hawaii, California'' (Base of Operations: Ala Wai Harbor, Honolulu, HI)

—*Vessel Length and Type:* 49′4″ Auxiliary Sail catamaran, multi hull

The complete application is available for review identified in the DOT docket as MARAD 2023–0157 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0157 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16833 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0169]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: BELLA (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0169 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0169 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0169, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel BELLA is:

—*Intended Commercial Use of Vessel:* ''Sailing Cruises and Tours.''
—*Geographic Region Including Base of Operations:* ''North Carolina, South Carolina, Georgia, Florida, Puerto Rico.'' (Base of Operations: Wrightsville Beach, NC)
—*Vessel Length and Type:* 45′ Catamaran

The complete application is available for review identified in the DOT docket as MARAD 2023–0169 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English.

We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0169 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16826 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0165]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ROSE MAE (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0165 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0165 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0165, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ROSE MAE is:

—*Intended Commercial Use of Vessel:* ''Sunset charter/sailing charter part time.''

—*Geographic Region Including Base of Operations:* ''Texas, Louisiana, Florida.'' (Base of Operations: Crystal Beach, TX)

—*Vessel Length and Type:* 44′ 2″ Catamaran

The complete application is available for review identified in the DOT docket as MARAD 2023–0165 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2023–0165 or visit the Docket

Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16834 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2023–0166]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: EVA ELAINE II (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before September 6, 2023.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2023–0166 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2023–0166 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2023–0166, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Email: *patricia.hagerty@dot.gov,* 202 366–0903.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel EVA ELAINE II is:

—*Intended Commercial Use of Vessel:* ''Charter vessel for halibut sport fishing (a six pack boat)—no more than six clients per trip. I have guided halibut clients for 23 years in the Cook Inlet area and am CG licensed.''

—*Geographic Region Including Base of Operations:* ''Alaska.'' (Base of Operations: Homer, AK)

—*Vessel Length and Type:* 31′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2023–0166 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search

MARAD–2023–0166 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2023–16829 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2023–0056]

Pipeline Safety: Pipeline Safety Research and Development Forum

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice of public meeting and webcast.

SUMMARY: This notice announces a public forum on Research and Development for pipeline safety titled ''Pipeline Safety Research and Development Forum 2023.'' PHMSA periodically holds this forum to help generate a national research agenda that identifies technical challenges and fosters solutions to improve pipeline safety and protect the environment.

DATES: The forum will be held October 31–November 1, 2023, from 8:00 a.m. to 4:30 p.m. On-site registration will begin at 7:00 a.m. on both days. Online preregistration will open on Tuesday, August 8, 2023, and close on Friday, October 20, 2023. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, should notify Andrea Ceartin, Engineering & Research Division, by phone at 406–577–6818, or email *andrea.ceartin@dot.gov* no later than October 4, 2023. For additional information, see the **ADDRESSES** section of this notice.

ADDRESSES: This public meeting and forum will be held in person at the Westin Crystal City Reagan National Airport, 1800 Richmond Highway, Arlington, Virginia 22202, with a webcast to include the opening technical presentations. Once finalized, the hotel reservation link, meeting agenda, and instructions on how to attend will be published on the public meeting registration page at *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=166.*

Presentations: Presentations will be available on the meeting website and at *https://regulations.gov,* Docket Number PHMSA–2023–0056, no later than 30 days following the meeting.

Submitting Comments: You may submit comments, identified by Docket Number. PHMSA–2023–0056, by any of the following methods:

- *Website:* The following website, *http://www.regulations.gov,* allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the online instructions for submitting comments.
- *Mail:* Docket Management System, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* DOT Docket Management System, located at 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, between 9:00 a.m. and 5:00 p.m. EST, Monday through Friday, except federal holidays.
- *Fax:* 202–493–2251. DOT Docket Management Facility. Confirmation notices for faxed comments will not be issued.
- *Instructions:* Identify Docket No. PHMSA–2023–0056 at the beginning of your comments. If you submit your comments by mail, please submit two copies. If you wish to receive confirmation that PHMSA received your comments, you must include a self-addressed stamped postcard. Internet users may submit comments at *http://www.regulations.gov.*
- *Note:* All comments received are posted without edits to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.
- *Confidential Business Information:* Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments in response to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to provide confidential treatment to information you give the agency by taking the following steps: (1) mark each page of the original document submission containing CBI as ''Confidential;'' (2) send PHMSA a copy of the original document with the CBI deleted along with the original, unaltered document; and (3) explain why the information you are submitting is CBI. Submissions containing CBI should be sent to Mary McDaniel, 1200 New Jersey Avenue SE, DOT: PHMSA—PHP–40, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket.
- *Privacy Act:* DOT may solicit comments from the public regarding certain general notices. DOT posts these

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

• *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. Alternatively, you may review the documents in person at the street address listed above.

FOR FURTHER INFORMATION CONTACT: Mary L. McDaniel, Acting Director of the Engineering and Research Division, by phone at 713–272–2847 or email at *mary.mcdaniel@dot.gov.*

SUPPLEMENTARY INFORMATION: The mission of PHMSA is to protect people and the environment by advancing the safe transportation of energy products and other hazardous materials that are essential to our daily lives.

Public Participation: The meeting and forum will be open to the public. Members of the public who wish to attend must register on the meeting website, including their names and organizational affiliation. PHMSA is committed to providing all participants with equal access to these meetings. If you need disability accommodations, please contact Janice Morgan by email at *janice.morgan@dot.gov.*

PHMSA is not always able to publish a notice in the **Federal Register** quickly enough to provide timely notification of last-minute changes that impact scheduled meetings. Therefore, individuals should check the meeting website listed in the **ADDRESSES** section of this notice or contact Janice Morgan by phone at 202–815–4705 or email at *janice.morgan@dot.gov* regarding any possible changes.

PHMSA invites public participation and public comment on the topics addressed in this public meeting and forum. Please review the **ADDRESSES** section of this notice for information on how to submit written comments.

Agenda Summary: The PHMSA Pipeline Safety R&D Forum is held to generate a national research agenda that identifies technical challenges; foster solutions to improve pipeline safety and protect the environment; and provide a venue for information exchange among key stakeholders, including the public, states, tribal governments, other federal agencies, industry, and international colleagues.

Issued in Washington, DC, on August 2, 2023, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2023–16802 Filed 8–4–23; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8874–A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 8874–A, Notice of Qualified Equity Investment for New Markets Credit.

DATES: Written comments should be received on or before October 6, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW, Washington, DC 20224 or by email to *pra.comments@irs.gov.* Please reference the information collection's ''OMB number 1545–2065'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington at (202) 317–5744, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *sara.l.covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Notice of Qualified Equity Investment for New Markets Credit.

OMB Number: 1545–2065.

Form Number: 8874–A.

Abstract: CDEs must provide notice to any taxpayer who acquires a qualified equity investment in the CDE at its original issue that the equity investment is a qualified equity investment entitling the taxpayer to claim the new markets credit. Form 8874–A is used to make the notification as required under section 1.45D–1(g)(2)(i)(A).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individual or households, Business or other for-profit.

Estimated Number of Respondents: 500.

Estimated Time Per respondent: 5 hours and 26 minutes.

Estimated Total Annual Burden Hours: 2,715.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including using automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 2, 2023.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2023–16851 Filed 8–4–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Internal Revenue Service Advisory Council; Meeting

AGENCY: Internal Revenue Service, Department of Treasury.

ACTION: Notice of meeting.

SUMMARY: The Internal Revenue Service Advisory Council will hold a public meeting.

DATES: The meeting will be held Thursday, September 7, 2023.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Ms. Anna Brown, Office of National Public Liaison, at 202–317–6564 or send an email to *PublicLiaison@irs.gov*.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 5 U.S.C. 10(a)(2) of the Federal Advisory Committee Act, that a public meeting of the Internal Revenue Service Advisory Council (IRSAC) will be held on Thursday, September 7, 2023, to discuss topics that may be recommended for inclusion in a future report of the Council. The virtual meeting will take place at 3:00 p.m. Eastern Time.

To confirm your attendance, members of the public may contact Anna Brown at 202–317–6564 or send an email to *PublicLiaison@irs.gov.* Attendees are encouraged to join at least five minutes before the meeting begins.

Should you wish the IRSAC to consider a written statement germane to the Council's work, please call 202–317–6564 or email *PublicLiaison@irs.gov* by September 5, 2023.

Dated: August 2, 2023.

John A. Lipold,

Designated Federal Official, Office of National Public Liaison, Internal Revenue Service.

[FR Doc. 2023–16797 Filed 8–4–23; 8:45 am]

BILLING CODE P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: August 10, 2023, 12:00 p.m. to 3:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 924 5715 1021, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJYpcu6pqzoqGNWu5SfY2GD3KSx9l6qe1PRL.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Audit Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Audit Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Audit Subcommittee Chair

For Discussion and Possible Subcommittee Action

The agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

Subcommittee action only to be taken in designated areas on the agenda.

IV. Review and Approval of Subcommittee Minutes From the May 4, 2023 Meeting—UCR Audit Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the May 4, 2023 Subcommittee meeting via teleconference will be reviewed. The Subcommittee will consider action to approve.

V. Discussion of Automatic Annual Renewal of UCR Registration—UCR Executive Director and Seikosoft Representative

For Discussion and Possible Subcommittee Action

The UCR Executive Director and Seikosoft Representative will lead a discussion on the issues involved in the voluntary, annual, and automatic renewal of UCR registrations. The Subcommittee may take action to recommend to the Board that Seikosoft design and implement a system using business rules recommended by the Subcommittee that allow for the voluntary, annual, and automatic renewal of UCR registrations.

VI. Discuss Options To Replace the Retreat Audit Program With a Program That Relies on Roadside Inspection Data—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, DSL Transportation Representative, and Seikosoft Representative

For Discussion and Possible Subcommittee Action

The UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, DSL Transportation Representative and Seikosoft Representative will lead a discussion on options to replace the Retreat Audit Program currently utilized by the States with an automated roadside inspection data driven audit for non-IRP and IRP-plated commercial motor vehicles (CMVs) and the motor carriers operating this type of registered equipment. The Subcommittee may take action to recommend to the Board that the current Retreat Audit Program be replaced with an automated roadside inspection data driven audit for non-IRP and IRP-plated commercial motor vehicles and the motor carriers operating this type of registered equipment.

VII. Discuss Options To Perform a Review That Reflects a More Accurate Number of Unregistered Motor Carriers of the UCR Universe in Shadow; MCMIS—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, DSL Transportation Representative and Seikosoft Representative

For Discussion and Possible Subcommittee Action

The UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, DSL Transportation Representative and Seikosoft Representative will lead a discussion on options and necessary steps for the NRS and State Auditors to review 2022/2023 unregistered motor carriers in Shadow MCMIS. The Subcommittee may take action to recommend to the Board that the UCR Plan perform a review that reflects a more accurate number of unregistered motor carriers of the UCR Universe in Shadow MCMIS.

VIII. Discuss Options To Add New Compliance Initiatives to the States' Annual Audit Reporting Requirements—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair

For Discussion and Possible Subcommittee Action

The UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair will lead a discussion on options to update the States' Annual Audit Reporting Requirements beginning with the 2023 UCR Registration Year. The Subcommittee may take action to recommend to the Board new compliance initiatives to the States' Annual Audit Reporting Requirements.

IX. General Discussion on the Direction of the Audit Subcommittee—UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair

The UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair will lead a general discussion on the current programs/projects of the Audit Subcommittee.

X. Update on Monthly Question and Answer Session for State Auditors—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, and UCR Executive Director

The UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair and UCR Executive Director will lead discussion on the value and continuation of a series of 60-minute virtual question and answer sessions.

XI. Other Business—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

XII. Adjournment—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, August 3, 2023 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2023–16921 Filed 8–3–23; 11:15 am]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0652]

Agency Information Collection Activity Under OMB Review: Request for Nursing Home Information in Connection With Claim for Aid and Attendance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0652.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0652'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 501(a)(2), 1115(1)(E), 1311(c), 1315(h), 1502, and 5503.

Title: Request for Nursing Home Information in Connection with Claim for Aid and Attendance (VA Form 21–0779).

OMB Control Number: 2900–0652.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21–0779 is used to gather the necessary information to determine eligibility for pension and aid and attendance benefits based on nursing home status. The form also requests information regarding Medicaid status and nursing home care charges, so VA can determine the proper rate of payment.

No changes have been made to this form. The respondent burden has decreased due to the estimated number of receivables averaged over the past year.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 88 FR 103 on May 30, 2023, page 34566.

Affected Public: Private sector.

Estimated Annual Burden: 2,895 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 17,367.

By direction of the Secretary.

Dorothy Glasgow,

VA PRA Clearance Officer (Alt), Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–16751 Filed 8–4–23; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

Vol. 88 Monday,

No. 150 August 7, 2023

Book 2 of 2 Books

Pages 52261–53348

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.

Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 418, 422, 423, 424, 425, 455, 489, 491, 495, 498, and 600

[CMS–1784–P]

RIN 0938–AV07

Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

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

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; payment for dental services inextricably linked to specific covered medical services; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare and Medicaid provider and supplier enrollment policies, electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act); updates to the Ambulance Fee Schedule regulations and the Medicare Ground Ambulance Data Collection System; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; expansion of the diabetes screening and diabetes definitions; pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners; appropriate use criteria for advanced diagnostic imaging; early release of Medicare Advantage risk adjustment data; a social determinants of health risk assessment in the annual wellness visit and Basic Health Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 11, 2023.

ADDRESSES: In commenting, please refer to file code CMS–1784–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1784–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1784–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786–6312, and Morgan Kitzmiller, (410) 786–1623, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Kris Corwin, (410) 786–8864, for issues related to the comment solicitation on strategies for updates to practice expense data collection and methodology.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to caregiver training services, community health integration services, social determinants of health risk assessment, and principal illness navigation services.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Kris Corwin, (410) 786–8864, Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Tamika Brock, (312) 886–7904, for issues related to teaching physician services.

Lindsey Baldwin, (410) 786–1694, Regina Walker-Wren, (410) 786–9160, Erick Carrera, (410) 786–8949, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to advancing access to behavioral health.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to PFS payment for evaluation and management services.

Morgan Kitzmiller, (410) 786–1623, for issues related to geographic practice cost indices (GPCIs).

Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to payment of skin substitutes.

Pamela West, (410) 786–2302, for issues related to supervision of outpatient therapy services, KX modifier thresholds, diabetes self-management training (DSMT) services, and DSMT telehealth services.

Laura Ashbaugh, (410) 786–1113, and Erick Carrera, (410) 786–8949, Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to dental services inextricably linked to specific covered medical services.

Laura Kennedy, (410) 786–3377, Adam Brooks, (202) 205–0671, and Rachel Radzyner, (410) 786–8215, for issues related to Drugs and Biological Products Paid Under Medicare Part B.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to complex drug administration.

Laura Ashbaugh, (410) 786–1113, Ariana Pitcher, *ariana.pitcher@cms.hhs.gov,* Rasheeda Arthur, (410) 786–3434, or *CLFS_Inquiries@cms.hhs.gov* for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC–PPS@cms.hhs.gov,* for issues related to FQHC payments.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov,* for issues related to RHC and FQHC Conditions for Certification or Coverage.

Kianna Banks (410) 786–3498 and Cara Meyer (667) 290–9856, for issues related to RHCs and FQHCs definitions of staff.

Sarah Fulton, (410) 786–2749, for issues related to pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners.

Lindsey Baldwin, (410) 786–1694, Ariana Pitcher, *ariana.pitcher@cms.hhs.gov,* or *OTP_Medicare@cms.hhs.gov,* for issues related to Medicare coverage of opioid use

disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology.

Lucy Bertocci, (667) 290–8833, or *SharedSavingsProgram@cms.hhs.gov,* for inquiries related to Shared Savings Program advance investment payments, and eligibility requirements.

Rachel Radzyner, (410) 786–8215, and Michelle Cruse, (443) 478–6390, for issues related to preventive vaccine administration services.

Mollie Howerton (410) 786–5395, for issues related to Medicare Diabetes Prevention Program.

Sarah Fulton (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging.

Frank Whelan, (410) 786–1302, for issues related to Medicare and Medicaid provider and supplier enrollment regulation updates.

Daniel Feller (410) 786–6913 for issues related to expanding diabetes screening and definitions.

Daniel Feller (410) 786–6913 for issues related to a social determinants of health risk assessment in the annual wellness visit.

Mei Zhang, (410) 786–7837, and Kimberly Go, (410) 786–4560, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786–1542, or *AmbulanceDataCollection@cms.hhs.gov,* for issues related to the Ambulance Fee Schedule (AFS) and the Medicare Ground Ambulance Data Collection System.

Mary Rossi-Coajou (410) 786–6051, for issues related to hospice Conditions of Participation.

Cameron Ingram (410) 409–8023 for issues related to Histopathology, Cytology, and Clinical Cytogenetics Regulations under CLIA of 1988.

Meg Barry (410) 786–1536, for issues related to the Basic Health Program (BHP) provisions.

Renee O'Neill, (410) 786–8821, or Sophia Sugumar, (410) 786–1648, for inquiries related to Merit-based Incentive Payment System (MIPS).

Richard Jensen, (410) 786–6126, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2024 PFS proposed rule, refer to item CMS–1784–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

This major annual rule proposes to revise payment polices under the Medicare PFS and makes other policy changes, including proposals to implement certain provisions of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328, September 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major proposed rule includes proposals regarding other Medicare payment policies described in sections III. and IV. of this proposed rule.

This rulemaking proposes to update the Rural Health Clinic (RHC) and Federally Qualified Health Clinic (FQHC) Conditions for Certification and Conditions for Coverage (CfCs), respectively, to implement the provisions of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328, December 29, 2022), now allowing payment under Medicare Part B for services furnished by a Marriage and Family Therapist (MFT) or Mental Health Counselor (MHC).

This rulemaking would also update the Hospice Conditions of Participation (CoPs) to implement division FF, section 4121 of the CAA 2023 regarding the addition of marriage and family therapists (MFTs) or mental health counselors (MHCs) as part of the hospice interdisciplinary team and would make changes to the hospice personnel requirements. This rulemaking would also seek to further advance Medicare's overall value-based care strategy of growth, alignment, and equity through the Medicare Shared Savings Program (MSSP) and the Quality Payment Program (QPP). The structure of the programs enables us to develop a set of tools for measuring and encouraging improvements in care, which may support a shift to clinician payment over time into Advanced Alternative Payment Models (APMs) and accountable care arrangements which reduce care fragmentation and unnecessary costs for patients and the health system.

This rulemaking would also update the Ambulance Fee Schedule regulations to implement division FF, section 4103 of the CAA 2023 regarding the ground ambulance extenders provisions and would also provide further changes and clarifications to the

Medicare Ground Ambulance Data Collection System.

This rulemaking would also update Medicare and Medicaid provider and supplier enrollment regulations.

B. Summary of the Major Provisions

The statute requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

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In this major proposed rule, we are proposing to establish RVUs for CY 2024 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and provisions regarding several other Medicare Part B payment policies, Medicare and Medicaid provider and supplier enrollment policies, and other policies regarding programs administered by CMS.

Specifically, this proposed rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Social Security Act (the Act) (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Geographic Practice Cost Indices (GPCI) (section II.G.)
- Payment for Skin Substitutes (section II.H.)
- Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professional, and DSMT Telehealth Services (section II.I.)
- Advancing Access to Behavioral Health (section II.J.)
- Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services (section II.K.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs) (section III.C.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.)
- Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)
- Medicare Diabetes Prevention Program Expanded Model (section III.I.)
- Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.J.)
- Medicare and Medicaid Provider and Supplier Enrollment (section III.K.)
- Expand Diabetes Screening and Diabetes Definitions (section III.L.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.M.)
- Proposed Changes to the Regulations Associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS) (section III.N.)
- Hospice: Changes to the Hospice Conditions of Participation (section III.O.)
- RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (section III.P.)
- Changes to the Basic Health Program Regulations (section III.Q.)
- Updates to the Definitions of Certified Electronic Health Record Technology (section III.R.)
- A Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.)
- Updates to the Quality Payment Program (section IV.)
- Collection of Information Requirements (section V.)
- Response to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

3. Summary of Costs and Benefits

We have determined that this proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

In accordance with section 1848 of the Act, CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a

service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the Relative Value Scale Update Committee (RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by cross-walking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a cross-walked PE/HR, we instead used the PPIS based PE/HR. We use cross-walks for specialties that did not participate in the PPIS. These cross-walks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2024 PFS proposed rule PE/HR'' on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of

total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 52983) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected

specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- *Cross-walk certain low volume physician specialties:* Cross-walk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Cross-walk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time

accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate) − life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes
usage = variable, see discussion below in this proposed rule
price = price of the particular piece of equipment
life of equipment = useful life of the particular piece of equipment
maintenance = factor for maintenance; 0.05
interest rate = variable, see discussion below in this proposed rule

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different

types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 3.

TABLE 3: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We are not proposing any changes to the equipment interest rates for CY 2024.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

In the past, we have stated that we believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to assure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the Medicare Economic Index (MEI). In the past, we have proposed (and subsequently, finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the MEI cost shares are updated, we would typically propose to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the rebased and revised MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described ''3. Adjusting RVUs To Match PE Share of the Medicare Economic Index (MEI)'' of the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the CY 2023 PFS final rule (87 FR 69688 through 69711), we finalized to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by physicians in furnishing physicians' services. We also finalized a delay of the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the rebased and revised MEI (87 FR 69414 through 69416). Because we finalized significant methodological and data source changes to the MEI in the CY 2023 PFS final rule and significant time has elapsed since the last rebasing and revision of the MEI in CY 2014, we believed that delaying the implementation of the finalized CY

2023 rebased and revised MEI was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in the CY 2023 PFS final rule (87 FR 69429 through 69432), where we reviewed our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. We also solicited comment in the CY 2023 PFS proposed rule on when and how to best incorporate the CY 2023 rebased and revised MEI into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. We presented the impacts of implementing the rebased and revised MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period in the CY 2023 PFS proposed rule. We also solicited comment on other implementation strategies for potential future rulemaking in the CY 2023 PFS proposed rule. In the CY 2023 PFS final rule, we discussed that many commenters supported our proposed delayed implementation and many commenters expressed concerns with the redistributive impacts of the implementation of the rebased and revised MEI in PFS ratesetting. Many commenters also noted that the AMA has said it intends to collect practice cost data from physician practices in the near future which could be used to derive cost share weights for the MEI and RVU shares.

In light of the AMA's intended data collection efforts in the near future and because the methodological and data source changes to the MEI finalized in the CY 2023 PFS final rule would have significant impacts on PFS payments, we continue to believe that delaying the implementation of the finalized 2017-based MEI cost weights for the RVUs is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Therefore, we are not proposing to incorporate the 2017-based MEI in PFS ratesetting for CY 2024.

As discussed above, in the CY 2023 PFS rulemaking, we finalized to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing physicians' services. The final 2017-based MEI relies on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership, not limited to only self-employed physicians. The 2006-based MEI relied on the 2006 AMA PPIS survey data; as of this CY 2024 rulemaking, this survey had not been updated. Given the changes in the physician and supplier industry and the time since the last update to the base year, we finalized a methodology that would allow us to update the MEI on a consistent basis in the future. The 2017-based MEI cost weights are derived predominantly from the annual expense data from the U.S. Census Bureau's Services Annual Survey (SAS, *https://www.census.gov/programs-surveys/sas.html*). We supplement the 2017 SAS expense data by using several data sources to further disaggregate compensation costs and all other residual costs (87 FR 69688 through 69708).

We continue to review more recently available data from the Census Bureau Services Annual Survey, the main data source for the major components of the 2017-based MEI weights. Data is currently available through 2021. Given that the impact of the PHE may influence the 2020 and 2021 data, we continue to evaluate whether the recent trends are reflective of sustained shifts in cost structures or were temporary as a result of the COVID–19 PHE. The 2022 data from the Services Annual Survey will be available later this year. We will monitor that data and any other data that may become available related to physician services' input expenses and will propose any changes to the MEI, if appropriate, in future rulemaking.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2024 direct PE input public use files, which are available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the

complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases, the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2023, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update, using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing interested parties the opportunity to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2024, we are proposing to update the price of 16 supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2023 PFS final rule. The 16 supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 14, CY 2024 Invoices Received for Existing Direct PE Inputs.

We are not proposing to update the price of another eleven supplies which were the subject of public submission of invoices. Our rationale for not updating these prices is detailed below:

- Extended external ECG patch, medical magnetic tape recorder (SD339): We received additional invoices for the SD339 supply from an interested party. Upon review of the invoices, we determined that they contained the identical price point that we previously incorporated into last year's rule when we finalized a price of $260.35 for the supply item (87 FR 69514 through 69516). Since these invoices did not contain any new information, we are maintaining the previously finalized price of $260.35 for the SD339 supply.
- Permanent marking pen (SL477), Liquid coverslip (Ventana 650–010) (SL479), EZ Prep (10X) (Ventana 950–102) (SL481), Cell Conditioning 1 (Ventana 950–124) (SL482), and Hematoxylin II (Ventana 790–2208) (SL483): We received invoices from interested parties for use in updating the price of these laboratory supplies. In each case, however, we were able to find the same supply item available for sale online at the current price or cheaper. Therefore, we do not believe that the submitted invoices represent typical market pricing for these supplies and we are not proposing to update their prices.
- Mask, surgical (SB033), scalpel with blade, surgical (#10–20) (SF033), eye shield, non-fog (SG049), gauze, non-sterile 4in x 4in (SG051), and towel, paper (Bounty) (per sheet) (SK082): We received invoices from interested parties for use in updating the price of these common supply items. In each case, we received a single invoice and once again we were able to find the same supply items available for sale online at the current price or cheaper. Generally speaking, we avoid updating the price for common supply items like the SB033 surgical mask (included in approximately 380 HCPCS codes) based on the submission of a single invoice, as an invoice unrepresentative of current market pricing will have far-reaching effects across the PFS. We did not find that the typical price for a surgical mask had increased by more than 60% since the supply and equipment pricing update concluded in CY 2022, and as such we are maintaining the current price for these supply items.

(1) Invoice Submission

We remind readers that we routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

c. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We believed it was important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we cross-walked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands

of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then cross-walked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data, as opposed to mean BLS wage data, in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized the use of a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the implementation of the clinical labor pricing update over 4 years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. (86 FR 65025) An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 4.

TABLE 4: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Updates

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64 rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we proposed this $0.64 rate for the L037B clinical labor type for CY 2023; we also proposed a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We also proposed the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032).

Based on comments received on the CY 2023 proposed rule, we finalized a change in the descriptive text of the L041A clinical labor type from ''Angio Technician'' to ''Vascular Interventional Technologist''. We also finalized an update in the pricing of three clinical labor types: from $0.60 to $0.84 for the Vascular Interventional Technologist (L041A), from $0.63 to $0.79 for the Mammography Technologist (L043A), and from $0.76 to $0.78 for the CT Technologist (L046A) based on submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey (87 FR 69422 through 69425).

(2) CY 2024 Clinical Labor Pricing Update Proposals

We did not receive new wage data or other additional information for use in clinical labor pricing from interested parties prior to the publication of the CY 2024 PFS proposed rule. Therefore, our proposed clinical labor pricing for CY 2024 is based on the clinical labor pricing that we finalized in the CY 2023 PFS final rule, incremented an additional step for Year 3 of the update:

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TABLE 5: Proposed CY 2024 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y3 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.268	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.335	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.420	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.410	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.495	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.375	18%
L035A*	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	0.534	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.423	19%
L037B*	Histotechnologist	BLS 29-2010	0.37	0.64	0.573	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.663	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.498	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	0.460	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	0.485	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	0.545	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.383	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	0.488	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.555	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.579	62%
L041A*	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	0.731	104%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.575	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.575	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.578	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.585	52%
L043A*	Mammography Technologist	ASRT Wage Data	0.43	0.79	0.702	84%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.683	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.780	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.638	56%
L046A	CT Technologist*	ASRT Wage Data	0.46	0.78	0.703	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.688	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.688	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.643	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.643	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.761	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.703	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.703	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.793	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.793	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.698	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.705	51%
L051C	RN/CORF	L051A	0.51	0.76	0.698	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.738	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.725	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.818	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.753	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.805	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.779	50%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Rate Per Minute	Y3 Phase-In Rate Per Minute	Total % Change
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.570	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.840	44%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.409	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	1.986	41%

As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the course of the 4-year transition period. We updated the pricing of a number of clinical labor types in the CY 2022 and CY 2023 PFS final rules in response to information provided by commenters. For the full discussion of the clinical labor pricing update, we direct readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

d. Technical Corrections to Direct PE Input Database and Supporting Files

Following the publication of the CY 2023 PFS proposed rule, an interested party notified CMS that CPT code 86153 (*Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); physician interpretation and report, when required*) appeared to be missing its work time in the Physician Work Time public use file. We reviewed the request from the interested party and determined that this was indeed an unintended technical error; we stated in the CY 2013 PFS final rule that we were finalizing 0 minutes pre-service time, 20 minutes intraservice time, and 0 minutes post-service time to CPT code 86153 (77 FR 69059), however work time was inadvertently completely missing for this code. Therefore, we are proposing to add the correct 20 minutes of intraservice work time to CPT code 86153 for CY 2024.

5. Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology

a. Background

The AMA PPIS was first introduced in 2007 as a means to collect comprehensive and reliable data on the direct and indirect PEs incurred by physicians (72 FR 66222). In considering the use of PPIS data, the goal was to improve the accuracy and consistency of PE RVUs used in the PFS. The data collection process included a stratified random sample of physicians across various specialties, and the survey was administered between August 2007 and March 2008. Data points from that period of time that are integrated into PFS calculations today. In the CY 2009 PFS proposed rule (73 FR 38507 through 3850), we discussed the indirect PE methodology that used data from the AMA's survey that predated the PPIS. In CY 2010 PFS rulemaking, we announced our intent to incorporate the AMA PPIS data into the PFS ratesetting process, which would first affect the PE RVU. In the CY 2010 PFS proposed rule, we outlined a 4-year transition period, during which we would phase in the AMA PPIS data, replacing the existing PE data sources (74 FR 33554). We also explained that our proposals intended to update survey data only (74 FR 33530 through 33531). In our CY 2010 final rule, we finalized our proposal, with minor adjustments based on public comments (74 FR 61749 through 61750). We responded to the comments we received about the transition to using the PPIS to inform indirect PE allocations (74 FR 61750). In the responses, we acknowledged concerns about potential gaps in the data, which could impact the allocation of indirect PE for certain physician specialties and suppliers, which are issues that remain important today. The CY 2010 PFS final rule explains that section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, November 29, 1999) directed the Secretary to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. BBRA required us to establish criteria for accepting supplemental survey data. Since the supplemental surveys were specific to individual specialties and not part of a comprehensive multispecialty survey, we had required that certain precision levels be met in order to ensure that the supplemental data was sufficiently valid, and acceptable for use in the development of the PE RVUs. At the time, our rationale included the assumption that because the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary, and we did not propose to establish them for the use of the PPIS data (74 FR 61742). We noted potential gaps in the data, which could impact the allocation of indirect PE for certain physician and suppliers. The CY 2010 final rule adopted the proposal, with minor adjustments based on public comments, and explained that these minor adjustments were in part due to non-response bias that results when the characteristics of survey respondents differ in meaningful ways, such as in the mix of practices sizes, from the general population (74 FR 61749 through 61750).

Throughout the 4-year transition period, from CY 2010 to CY 2013, we gradually incorporated the AMA PPIS data into the PFS rates, replacing the previous data sources. The process involved addressing concerns and making adjustments as necessary, such as refining the PFS ratesetting methodology in consideration of interested party feedback. For background on the refinements that we considered after the transition began, we refer readers to discussions in the CY 2011–2014 final rules (75 FR 73178 through 73179; 76 FR 73033 through 73034; 77 FR 98892; 78 FR 74272 through 74276).

In the CY 2011 PFS proposed rule, we requested comments on the methodology for calculating indirect PE RVUs, explicitly seeking input on using survey data, allocation methods, and potential improvements (75 FR 40050). In our CY 2011 PFS final rule, we addressed comments regarding the methodology for indirect PE calculations, focusing on using survey data, allocation methods, and potential improvements (75 FR 73178 through 73179). We recognized some limitations of the current PFS ratesetting methodology but maintained that the approach was the most appropriate at the time. In the CY 2012 PFS final rule, we responded to comments related to indirect PE methodology, including concerns about allocating indirect PE to specific services and using the AMA

PPIS data for certain specialties (76 FR 73033 through 73034). We indicated that CMS would continue to review and refine the methodology and work with interested parties to address their concerns. In the CY PFS 2014 final rule, we responded to comments about fully implementing the AMA PPIS data. By 2014, the AMA PPIS data had been fully integrated into the PFS, serving as the primary source for determining indirect PE inputs (78 FR 74235). We continued to review data and the PE methodology annually, considering interested party feedback and evaluating the need for updates or refinements to ensure the accuracy and relevance of PE RVUs (79 FR 67548). In the years following the full implementation of the AMA PPIS data, we further engaged with interested parties, thought leaders and subject matter experts to improve our PE inputs' accuracy and reliability. For further background, we refer readers to our discussions in final rules for CY 2016–2022 (80 FR 70892; 81 FR 80175; 82 FR 52980 through 52981; 83 FR 59455 through 59456; 84 FR 62572; 85 FR 84476 through 84478; 86 FR 62572).

In our CY 2023 PFS final rule, we issued an RFI to solicit public comment on strategies to update PE data collection and methodology (87 FR 69429 to 69432). We solicited comments on current and evolving trends in health care business arrangements, the use of technology, or similar topics that might affect or factor into PE calculations. We remind readers that we have worked with interested parties and CMS contractors for years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear, but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology.

As described in last year's rule, we have continued interest in developing a roadmap for updates to our PE methodology that account for changes in the health care landscape. Of various considerations necessary to form a roadmap for updates, we reiterate that allocations of indirect PE continue to present a wide range of challenges and opportunities. As discussed in multiple cycles of previous rulemaking, our PE methodology relies on AMA PPIS data, which may represent the best aggregated available source of information at this time. However, we acknowledge the limitations and challenges interested parties have raised about using the current data for indirect PE allocations, which we have also examined in related ongoing research. We noted in last year's rule that there are several competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

Many commenters last year asked that CMS wait for the AMA to complete a refresh of AMA survey data. We responded to these comments by explaining the tension that waiting creates in light of concerns raised by other interested parties. Waiting for refreshed survey data would result in CMS using data nearly 20 years old to form indirect PE inputs to set rates for services on the PFS. We remind readers that many of the critical issues discussed in the background and history above are mainly unchanged and possibly would not be addressed by an updated survey alone but may also require revisions to the PFS ratesetting methodology.

b. Request for Information

We continue to encourage interested parties to provide feedback and suggestions to CMS that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Submissions should discuss the feasibility and burden of implementing any suggested adjustments and highlight opportunities to optimize the cadence, frequency, and phase-in of resulting adjustments. We continue to consider ways that we may engage in dialogue with interested parties to better understand how to address possible long-term policies and methods for PFS ratesetting. We believe some of those concerns may be alleviated by having ways to refresh data and make transparent how the information affects valuations for services payable under the PFS more accurately and precisely.

Considering our ratesetting methodology and prior experiences implementing new data, we are issuing a follow-up solicitation for general information. We seek comments from interested parties on strategies to incorporate information that could address known challenges we experienced in implementing the initial AMA PPIS data. Our current methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (for, example, we use supplemental survey data collected in 2003, as required by section 1848(c)(2)(H)(i) of the Act to set rates for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and provider types.

We also seek to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In light of the considerations discussed above, we request feedback on the following:

(1) If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPIS data would be less likely to over-allocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?

(2) Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable and accurate means to account for indirect PEs across various specialties or practice types?

(3) If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice-specific characteristics (for example, practice size, patient population served)?

(4) What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?

(5) Whether specific types of outliers or non-response bias may require different analytical approaches and methodological adjustments to integrate refreshed data?

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify

potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this proposed rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also considered information provided by other interested parties such as from the general medical-related community and the public. We conducted a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and groups may submit

codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes'').[1] In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2024 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for potentially misvalued codes by February 10th and we display these nominations on our public website, where we include the submitter's name and their associated organization for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the potentially misvalued code initiative. For CY 2024, we received 10 nominations concerning various codes. The nominations are as follows:

(1) CPT Code 59200

In the CY 2022 PFS proposed rule, an interested party nominated CPT code 59200 (*Insertion cervical dilator (e.g., laminaria, prostaglandin*)) (000 zero day global code) as potentially misvalued, because the direct PE inputs for this code do not include the supply item, Dilapan-S. Previous parties had initially sought to establish a Level II HCPCS code for Dilapan-S, but CMS did not find sufficient evidence to support that request. The same interested party then submitted Dilapan-S to be considered as a practice expense (PE) supply input to a Level I CPT code 59200 (86 FR 65045). This year, a different interested party has nominated CPT code 59200 again, and provided the same reasoning as to why this code is potentially misvalued.

[1] The research team and panels of experts at the Harvard School of Public Health developed the original work RVUs for most CPT codes, in a cooperative agreement with the Department of Health and Human Services (HHS). Experts from both inside and outside the Federal Government obtained input from numerous physician specialty groups. This input was incorporated into the initial PFS, which was implemented on January 1, 1992.

Specifically, the current nominee recommends adding 4 rods of Dilapan-S at $80.00 per unit, for a total of $320.00 to this one PE supply inputs, as a replacement for the current PE supply item—laminaria tent (a small rod of dehydrated seaweed that rehydrates, absorbing the water from the surrounding tissue). The laminaria tent is currently listed at $4.0683 per unit, with a total of 3 units, for a total of $12.20. The current nominee stated that Dilapan-S is more consistent and reliable, and suggested that it had higher patient satisfaction than the laminaria tent, and that it was less likely to cause leukocytosis. CPT code 59200 is a relatively low volume code, with respect to Medicare claims and, as the nominator has stated, this service is more typically billed for the Medicaid population, as evidenced by 1.3 million Medicaid claims for this service. Medicaid programs are able to set their own payment policies, which can be different from Medicare payment policies. The current Medicare payment for CPT code 59200 in CY 2023 is about $108.10 in the nonfacility/office setting, which is much less than the typical cost of the Dilapan-S supplies requested by the interested party. The requested 4 rods of Dilapan-S would increase the supply costs of CPT code 59200 by a factor of five and represent an enormous increase in the direct costs for the service.

We do not agree that CPT code 59200 is potentially misvalued, and we do not agree with interested parties that the use of the Dilapan-S supply would be typical for this service. By including the increased direct costs of the service ($320.00, the typical cost of four units of this supply item, Dilapan-S) in the valuation for this code, the cost of this service will expand both Medicare spending and cost sharing for any beneficiary who receives this service. The cost of Dilapan-S is over 19 times higher than the cost of the current supply item (laminaria tent) for CPT code 59200. We do agree with the nominator that CPT code 59200 is much more frequently reported in the Medicaid population, and therefore, we suggest that interested parties submit a request for new and separate Medicaid payments to Medicaid.

We are not proposing to consider this code as potentially misvalued for CY 2024, though we welcome comments on this nomination for further consideration. We are soliciting comments on CPT code 59200 and whether the absence of supply item Dilapan-S makes the nonfacility/office Medicare payment for this service potentially misvalued.

(2) CPT Code 27279

CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) (090 day global code) has been nominated as misvalued due to the absence of separate direct PE inputs for this 090 day global code in the nonfacility office setting. Currently, the PFS only prices CPT code 27279 in the facility setting, at about $826.85 for the physician's professional services, but the nominators are seeking separate direct PE inputs for this service to better account for valuation when performed in the nonfacility/office setting. These PE amounts for CPT code 27279 are expected to be approximately $21,897.63 in total, which is the Medicare outpatient payment amount for CY 2023.

The nominator claims that CPT code 27279 can be safely and effectively furnished in the nonfacility setting, and that this procedure has a low risk profile, similar to kyphoplasty (CPT codes 22513, 22514, and 22515), which is currently furnished in the nonfacility setting. The nominator describes Kyphoplasty as ''a percutaneous minimally invasive procedure depositing poly methyl methacrylate via canula into vertebral bodies near neural structures.'' The nominator states that permitting payment for direct PE inputs for CPT code 27279 in the nonfacility/office setting would increase access to this service for Medicare patients. One sample invoice for $17,985.00 with three units of the itemized supply item IFuse-3D Implant 7.0 mm × 55 mm, US ($5,995.00 per unit) was submitted with this nomination to illustrate the high direct PE costs for CPT code 27279, should CMS value this code in the nonfacility/office setting.

We are concerned about whether this 090 day surgical service can be safely and effectively furnished in the non-facility/office setting (for example, in an office-based surgical suite). We welcome comments on the nomination of CPT code 27279 for consideration as potentially misvalued.

(3) CPT Codes 99221, 99222, and 99223

An interested party nominated the Hospital Inpatient and Observation Care visit CPT codes 99221 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.*), 99222 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.*), and 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.)* as potentially misvalued. CMS reviewed these codes in the CY 2023 final rule (87 FR 69588) and established new physician work times and new work RVU payments for these codes. The nominator disagrees with these values and asserts that these ''facility-based codes are always inherently (or proportionately) more intense than E/M services provided in other settings [in particular],'' with patients presenting with potentially infectious diseases, such as meningitis; pneumonia; tuberculosis; HIV/AIDS; Ebola virus; Zika virus; and, most recently, SARS–CoV–2 and mpox, and that the inpatient setting has a predominance of more seriously ill patients, who are sometimes immunocompromised and/or have multiple drug interaction issues and/or with comorbidities, making them extraordinarily more complex than those patients typically found in the

office setting (with many of these infections being health care-associated infections and antibiotic-resistant bacterial infections). It should be noted that these new requests did not offer appreciably new information relative to last year's nomination/consideration.

The nominator seeks a new work RVU value of 1.92 for CPT code 99221, a new work RVU of 2.79 for CPT code 99222, and a new work value of 4.25 for CPT code 99223. Currently, CPT code 99221 has a work RVU of 1.63, a reduction of 15.1 percent from its 1.92 work RVU from CY 2022. CPT code 99222 had a work RVU of 2.61 in CY 2022 and is now at 2.60. CPT code 99223 had a work RVU of 3.86 in CY 2022. It now has a value of 3.50, which is a reduction of 9.3 percent. The nominator has requested that the work RVU for CPT code 99221 be restored back to 1.92, that the work RVU of CPT code 99222 be increased to 2.79, and that the work RVU of CPT code 99223 be increased to 4.25 (please see Table 6 for a comparison of work RVU values for CY 2022, CY 2023, and of those requested by the nominator).

TABLE 6: A Comparison of Work RVU values for CY 2022, CY 2023, and Those Requested by the Nominator

CPT Code	CY 2022 Work RVU	CY 2023 Work RVU	Requested Work RVU
99221 - 1st hosp ip/obs sf/low 40	1.92	1.63	1.92
99222 - 1st hosp ip/obs moderate 55	2.61	2.60	2.79
99223 - 1st hosp ip/obs high 75v	3.86	3.50	4.25

After consideration of this nomination and their requests for higher work RVUs for CPT codes 99221, 99222, and 99223, we are proposing to maintain the values that we finalized for these codes in the CY 2023 PFS final rule (87 FR 69588). Even so, we welcome comments on the nomination of these codes as potentially misvalued.

(4) CPT Codes 36514, 36516, 36522

An interested party nominated CPT codes 36514 (*Therapeutic apheresis; for plasma pheresis*), 36516 (*Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion*), and 36522 (*Photopheresis, extracorporeal*) (all 000 zero day global codes) as potentially misvalued. The interested party stated that the direct PE of clinical labor L042A, ''RN/LPN'' (for labor rate of $0.525 per minute) was incorrect and should be changed to a more specific entry of ''a therapeutic apheresis nurse specialist (RN)'' (for a labor rate of about $1.06 to $1.14 per minute), which would approximately double all three of these codes' clinical labor PE entries. In addition, the nominator disagrees with the current direct PE of supply item SC085, ''Tubing set, plasma exchange'' at $186.12 per item, and believes that this should be worth $248.77 per item with CPT code 36514, using a quantity of one item. The nominator believes that supply item SC084, ''Tubing set, blood warmer,'' that we currently have listed at $8.01 per item, should be worth $14.71 per item with CPT code 36514, also using a quantity of one item. Sample invoices (not actual invoices) were submitted for illustration and support. We welcome comments on the nomination of these codes as potentially misvalued, or not.

(5) CPT Codes 44205 and 44204

An interested party nominated CPT code 44205 (*Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy*), as potentially misvalued, requesting that payment for this code be made equivalent to the payment for CPT code 44204 (*Laparoscopy, surgical; colectomy, partial, with anastomosis*), which is a higher amount. Both codes are 090 day global codes, currently valued only in the facility setting. CPT code 44204 has a total RVU of 45.62 for CY 2023 and CPT code 44205 has a total RVU of 39.62 for CY 2023, with a difference of 6.00 RVUs. CPT code 44204 is associated with 5 to 6 percent more physician work time: 455.0 minutes in total, as compared to 428.5 minutes in total for CPT code 44205. The work RVU for CPT code 44204 is also 15 percent higher than the work RVU for CPT code 44205. The direct PE entries for both codes are the same with regard to supplies, equipment, and clinical labor, except that in the clinical labor and equipment entries, the number of usage minutes is higher for CPT code 44204.

Though these two codes appear to be similar, they are still different in their purpose, physician work times, and direct PEs, with CPT code 44204 involving more time and resources (and having a higher payment, accordingly). For these reasons, we are not inclined to agree that CPT code 44205 is potentially misvalued when compared to CPT code 44204, or to modify this payment differential by paying a higher amount for CPT code 44205. We are soliciting feedback regarding the nomination of CPT code 44205 as potentially misvalued.

(6) CPT Codes 93655 and 93657

An interested party nominated CPT codes 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure))* and 93657 *(Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)),* as potentially misvalued. These two add-on codes were part of our code review in the cardiac ablation code family in the CY 2022 (86 FR 65108) and CY 2023 (87 FR 69516) final rules.

The nominator reiterates that the primary procedures involve ''high intensity clinical decision making, complexity in the intraoperative skills required for treatment, morbidity/mortality risks to the patient, and work intensity'' and that the work RVUs for both of these add-on codes should reflect the AMA RUC recommended 7.00 work RVUs. We disagreed with this value in CY 2022, and we continue to believe that a work RVU of 5.50 is appropriate for the 60 minutes of physician service time for both codes. We see no reason to reconsider our valuation of CPT codes 93655 and

93657 for CY 2022 or CY 2023, and we do not consider these codes to be potentially misvalued now. We are not proposing to nominate these codes as potentially misvalued for CY 2024.

(7) CPT Code 94762 and 95800

An interested party nominated CPT code 94762 (*Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)*) as potentially misvalued due to the PE items listed for this code, which were last reviewed in 2009. There is no physician work/professional component associated with this code. The nominator states that the technology behind this code has changed considerably over the last 14 years, and that the listed equipment items for CPT code 94762, EQ212 ''pulse oxymetry recording software (prolonged monitoring)'' and EQ353 ''Pulse oximeter 920 M Plus'' are now typically found in a one-time use supply item: SD263 ''WatchPAT pneumo-opt slp probes'' (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device) costing $99.00 each, derived from two sample invoices (not actual invoices) that were included with the nomination. According to our PE supply list, item SD263 costs $73.32, which is $25.68 less than the amounts found in the sample invoices submitted by the nominators. The nominator retains equipment item EQ212 ''pulse oxymetry recording software (prolonged monitoring)'', and replaces equipment item EQ353 with ED021, a ''computer, desktop, w-monitor.'' Payment for CPT code 94762 is currently $25.75 in the nonfacility office setting. There were 122,207 allowed service claims for CPT code 94762 in CY 2021. The facility payment amount for CPT code 94762 under the Medicare Hospital Outpatient Prospective Payment System (OPPS) is currently $145.43.

The same interested party who nominated CPT code 94762 also nominated CPT code 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time*) as potentially misvalued, requesting that CMS update PE items for this code, which were last reviewed in 2017. CPT code 95800 currently includes the entry of a one-time use supply item, SD263 ''WatchPAT pneumo-opt slp probes'' (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device), which costs $73.32 per item, in contrast to the pricing in the sample invoice—$99.00 each (case of 12 × $99.00 = $1,188.00). This is a $25.68 difference in this supply item's cost.

The nominator excludes the current equipment for this code (EQ335 ''WatchPAT 200 Unit with strap, cables, charger, booklet and patient video'' and EQ336 ''Oximetry and Airflow Device'') and instead includes ED021 (''computer, desktop, w-monitor'') in the PE for this code. We note that we have not previously included ED021 as a specialized equipment item dedicated to this function (and EQ212 ''pulse oxymetry recording software (prolonged monitoring)'' is also not included in the PE for CPT code 95800, as it is with CPT code 94762). The nominator included the PE listings for CPT code 93245 (*Heart rhythm recording, analysis, interpretation and report of continuous external EKG over more than 1 week up to 1 weeks*) as an example of how PE supply items for CPT code 95800 should be structured, but this code includes a supply item, SD339 ''extended external ECG patch, medical magnetic tape recorder'' and equipment item ED021 ''computer, desktop, w-monitor,'' which is presumed to be used to record the data from the ECG patch and to be used to analyze this data. CMS currently pays a total of $150.80 for CPT code 95800 in the non-facility office setting, and there were 53,793 allowed services for this code in CY 2021.

There is not clear evidence whether the WatchPAT One Device needs, or does not need, the specific monitoring and recording system (equipment item EQ212 ''pulse oxymetry recording software (prolonged monitoring)'') for CPT code 95800 as opposed to any other system/process. The interested party has requested the practice expense changes discussed above as support for their argument that these CPT codes are potentially misvalued (See Table 7.)

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TABLE 7: Listing of Nominator's Practice Expense Items for Addition or Deletion to CPT codes 94762 and 95800

CPT code	Current Equipment Code	Equipment Description	Non-Facility/ Office Equipment PE Cost	Equipment Status	Current Supply Code	Supply Description	Non-Facility/ Office Supply PE Cost	Supply Status
94762	EQ212	pulse oxymetry recording software (prolonged monitoring) (480 min)	$0.7360	Retain				
94762	EQ353	Pulse oximeter 920 M Plus (480 min)	$7.1155	Delete	SD263	WatchPAT pneumo-opt slp probes" (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device)	$73.32 Or $99.00	Add
95800	EQ335	WatchPAT 200 Unit with strap, cables, charger, booklet and patient video	$4.7071	Delete				
95800	EQ336	Oximetry and Airflow Device	$4.5454	Delete				
95800	ED021	computer, desktop, w-monitor (assume 480 min)	$2.5339	Add	SD263	WatchPAT pneumo-opt slp probes" (extended external overnight pulse oximeter device probe and battery with bluetooth, medical magnetic tape recorder) (WatchPAT One Device)	$73.32 Or $99.00	Retain

We welcome comments as to whether or not these codes are potentially misvalued.

(8) CPT Codes 0596T and 0597T

An interested party has nominated CPT codes 0596T (*Initial insertion of temporary valve-pump in female urethra*) and 0597T (*Replacement of temporary valve-pump in female urethra*) as potentially misvalued due to MAC pricing, which is determined on a case-by-case basis. These temporary CPT category III codes are all procedure status ''C'' (contractor priced), and the interested party is seeking status ''A'' (for active payment status) to account for physician work, nonfacility PE, and professional liability costs. The nominator states that the MAC-determined payment amounts have been inappropriately low, and do not account for the time and the work that the physician expends for these services, or for all of the PE costs associated with the Vesiflo inFlow System. For CPT code 0596T, the nominator expects a physician to spend 60 minutes of work on installing this Vesiflo inFlow System. The nonfacility office PE items include a power table, a mayo stand, an examination light, clinical labor time of a RN/LPN/MTA totaling to 73 minutes, and a list of supplies summing to $1,902.76, primarily from the inFlow Measuring Device of $140.00, the inflow Device of $495.00, and the inflow Activator Kit of $1,250.00, making up about 99 percent of the total cost of supplies.

For CPT code 0597T, the nominator expects a physician to spend 25 minutes of work replacing this Vesiflo inFlow System. The nonfacility office PE items include a power table, a mayo stand, an examination light, clinical labor time of a RN/LPN/MTA totaling to 38 minutes, and a list of supplies summing to $505.30, primarily from the inflow device of $495.00, making up about 98 percent of the total cost of supplies. A sample invoice is included in this nomination (as opposed to an actual invoice).

We welcome comments as to whether or not these two temporary category II CPT codes, CPT codes 0596T and 0597T, are potentially misvalued, and whether these codes should remain contractor priced or not.

(9) CPT Code 93000

An interested party has nominated CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*) as potentially misvalued, arguing that we should increase Medicare payment for CPT code 93000 to $35.64, when used in conjunction with other supplies and services, to adequately compensate practitioners for their PE item costs for: (1) $6.10 for EKG leads; (2) $21.19 for a nurse visit of typically 5 minutes time (as illustrated by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.)*); and (3) $7.64 for the interpretation and report for the EKG service (as illustrated by CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only*). The interested party is asking for the grouping of these services to be valued at $35.64 (the actual sum of these inputs is $34.93). No invoices or other evidence were provided for consideration.

For CY 2023, the national payment amounts under the PFS for CPT codes 93000, 93010, and 99211 in the nonfacility office setting are as follows:

- CPT code 93000; total RVUs 0.43 × CF $33.8872 = $14.57.
- CPT code 93010; total RVUs 0.24 × CF $33.8872 = $8.13.
- CPT code 99211; total RVUs 0.69 × CF $33.8872 = $23.38.
- Sum total $46.08.

After consideration, we are not proposing to nominate CPT code 93000 as potentially misvalued for CY 2024. The sum of a mix of services is not a persuasive indication that one code—in this case, CPT code 93000—is potentially misvalued.

(10) 19 Therapy codes

An interested party has nominated 19 therapy codes as potentially misvalued. These 19 therapy codes were last reviewed by CMS in the CY 2018 PFS final rule (82 FR 53073 through 53074). The interested party stated that the direct PE clinical labor minutes as recommended by the AMA Relative Value Scale Update Committee (RUC) and Healthcare Professional Advisory Committee (HCPAC) Review Board might have had inappropriate multiple procedure payment reductions (MPPR) applied to their PE clinical labor time entries. The nominators are now seeking correction for those clinical labor time entries, which, if adjusted in accordance with the recommendations of the nominators, would likely result in slightly higher or nominally changed payments for the 19 therapy codes.

We have reviewed the clinical labor time entries for these 19 therapy codes, and we are now reconsidering the values established in the CY 2018 final rule. We do not believe that MPPR should be applied to these 19 nominated therapy codes' clinical labor time entries (listed in Table 8), and as a result, we would like the AMA RUC HCPAC recommendations from January 2017 to be re-reviewed. We recommend nomination of these 19 codes as potentially misvalued for CY 2024, and we welcome comments on this nomination.

TABLE 8: 19 "Always Therapy" Service Codes Nominated for Potential Misvaluation

HCPCS 2023	LONG DESCRIPTION	CY 2023 STATUS CODE
97012	Application of mechanical traction	A
97014	Application of electrical stimulation	I
97016	Application of blood vessel compression device	A
97018	Application of hot wax bath	A
97022	Application of whirlpool therapy	A
97032	Application of electrical stimulation with therapist present, each 15 minutes	A
97033	Application of medication using electrical current, each 15 minutes	A
97034	Application of hot and cold baths, each 15 minutes	A
97035	Application of ultrasound, each 15 minutes	A
97110	Therapy procedure using exercise to develop strength, endurance, range of motion, and flexibility, each 15 minutes	A
97112	Therapy procedure to re-educate brain-to-nerve-to-muscle function, each 15 minutes	A
97113	Therapy procedure using water pool to exercises, each 15 minutes	A
97116	Therapy procedure for walking training, each 15 minutes	A
97140	Therapy procedure using manual technique, each 15 minutes	A
97530	Therapy procedure using functional activities	A
97533	Therapy procedure using sensory experiences	A
97535	Training for self-care or home management, each 15 minutes	A
97537	Training for community or work reintegration, each 15 minutes	A
97542	Evaluation for wheelchair, each 15 minutes	A
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care	A

Note: Status code A = Active code – separately paid under the PFS. Status code I = Invalid code – not valid for Medicare purposes.

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D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare Telehealth Services List to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site, and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare Telehealth Services List. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits. Some examples of other clinical benefits that we consider include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treatment.
  - Decreased pain, bleeding, or other quantifiable signs or symptoms.
  - Reduced recovery time.
- *Category 3:* In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the public health emergency (PHE) for the COVID–19 pandemic. This new category describes services that were added to the Medicare Telehealth Services List during the PHE, for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare Telehealth Services List. To add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns for patient safety if the service is furnished as a telehealth service.

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

++ Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare Telehealth Services List using the Category 3 criteria described above. In this proposed rule, we are considering additional requests to add services to the Medicare Telehealth Services List on a Category 3 basis using the previously described Category 3 criteria. The Medicare Telehealth Services List, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2024, requests to add services to the Medicare Telehealth Services List must have been submitted and received by February 10, 2023. Each request to add a service to the Medicare Telehealth Services List must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare Telehealth Services List, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2024

Under our current policy, we add services to the Medicare Telehealth Services List on a Category 1 basis when we determine that they are similar to services on the existing Medicare Telehealth Services List for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site, and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only

streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the Medicare Telehealth Services List that resemble those services already on the Medicare Telehealth Services List.

We also note that section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extends the telehealth policies enacted in the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) through December 31, 2024, if the PHE ends prior to that date, as discussed in section II.D.c. of this proposed rule.

We received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2024. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. The requested services are listed in Table 9.

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TABLE 9: CY 2024 Requests for Permanent Addition – Services Not Proposed for Permanent Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
Cardiovascular Procedures	93793	Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed
Cardiovascular and Pulmonary Rehabilitation	93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
	94625	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)
Deep Brain Stimulation	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
	95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)
Therapy	90901	Biofeedback training by any modality
	97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
	97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or

Service Type	HCPCS	Long Descriptor
		measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
Therapy	97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
	97750	Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes
	97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
Hospital Care, Emergency Department and Hospital	99221	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.
	99222	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.
	99223	Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.
	99234	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.
	99235	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.
	99236	Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.
	99238	Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter
	99239	Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter
	99281	Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional
	99282	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making
	99283	Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making
Health and Well-Being Coaching	0591T	Health and well-being coaching face-to-face; individual, initial assessment
	0592T	Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes
	0593T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes

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We remind interested parties that the criterion for adding services to the Medicare telehealth list under Category 1 is that the requested services are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare Telehealth Services List, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below, we find that none of the requested services listed in Table 9 1 met the Category 1 criterion.

(1) Cardiovascular Procedures

We received a request to permanently add CPT code 93793 *(Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling*

of additional test(s), when performed)) to the Medicare Telehealth Services List. We do not consider this service to be a Medicare telehealth service, because the service is not an inherently face-to-face service—a patient need not be present in order for the service to be furnished in its entirety. For example, in many instances, clinical staff will not change a patient's warfarin dosage as a result of the lab INR test result, and they may or may not confirm the need for a follow-up test via phone; either way there is no need for a face-to-face encounter with a practitioner. As we have explained in previous rulemaking (83 FR 59483), certain kinds of services that are furnished remotely using communications technology are not considered Medicare telehealth services and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of section 1834(m) of the Act and do not usually include patient interaction such as the remote interpretation of diagnostic tests. We do not consider CPT code 93793 to be a telehealth service under section 1834(m) of the Act or our regulation at § 410.78. Therefore, we are not proposing to add this service to the Medicare Telehealth Services List on a Category 1 basis.

(2) Cardiovascular and Pulmonary Rehab

We received multiple requests to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 93797 (*Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)*); and
- 94624 *(Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)).*

In the CY 2022 PFS final rule (86 FR 65048), we explained that some services were added temporarily to the Medicare Telehealth Services List on an emergency basis to allow practitioners and beneficiaries to have access to medically necessary care while avoiding both risk for infection and further burdening healthcare settings during the PHE for COVID–19. In the same rule, we considered available evidence and noted that as evidence evolves on this subject matter, we welcome further discussions with interested parties on the topic. In subsequent cycles of annual rulemaking, we have continued conversations with interested parties that furnish, support, and use Cardiovascular and Pulmonary Rehabilitation services. In our CY 2022 PFS final rule (86 FR 65055), we acknowledged that commenters provided a number of studies on the safety and efficacy of these services when furnished via telehealth, and we added the codes to the list on a temporary, Category 3 basis.

We note that some evidence submissions and ongoing discussions with interested parties have focused on the clinical benefits of patients receiving these services in the home. We note that, while demonstrating the clinical benefits of services is important to our decision whether to add a service to the Medicare Telehealth Services List, there are other considerations when deciding whether to add codes to the list on a permanent basis. For example, while the CAA, 2023, does extend certain COVID–19 PHE flexibilities, including allowing the beneficiary's home to serve as an originating site, such flexibilities are only extended through the end of CY 2024. Under current law, beginning on January 1, 2025, the beneficiary's home can be an originating site only for Medicare telehealth services furnished for: (1) the diagnosis, evaluation, or treatment of a mental health disorder; or (2) a beneficiary with a diagnosed substance use disorder (SUD) for purposes of treatment of the SUD or a co-occurring mental health disorder; or (3) monthly ESRD-related clinical assessments furnished to a beneficiary who is receiving home dialysis, beginning January 1, 2025. Therefore, in the absence of further action by Congress, CPT codes 93797 and 94626 will not be able to be furnished via telehealth to a beneficiary in the home beginning January 1, 2025. As such, we are not proposing to include these services permanently on the Medicare Telehealth Services List on a Category 1 basis. We are instead proposing to continue to include these services on the Medicare Telehealth Services List through CY 2024. We would then remove CPT codes 93797 and 94626 from the Medicare Telehealth Services List for CY 2025.

(3) Deep Brain Stimulation

We received a request to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming*);
- 95983 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional*); and
- 95984 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)*).

In our CY 2023 proposed rule (85 FR 45891), we explained that these services do not meet the Category 1 criterion for permanent addition to the Medicare Telehealth Services List. Additionally, we discussed concerns about whether the full scope of service elements could be furnished via two-way, audio-video communication technology, particularly since it is unclear whether the connection between the implanted device and the analysis/calibration equipment can be done remotely. Additionally, we are concerned about the immediate safety of the patient if the calibration of the neurostimulator were done incorrectly or if some other problem occurred. However, we did include these services on the Medicare Telehealth Services List on a temporary basis during the PHE to allow additional time for additional information to be gathered and presented. Based on this information, we believe there is some possible clinical benefit for these services when furnished via telehealth; however, there is not yet sufficient evidence available to consider the services for permanent addition under

the Category 2 criterion. We are proposing to keep these services on the Medicare Telehealth Services List for CY 2024. We would consider additional evidence in future rulemaking to determine whether to add the services to the Medicare Telehealth Services List on a permanent basis.

(4) Therapy

We received requests to add Therapy Procedures: CPT codes 97110, 97112, 97116; Physical Therapy Evaluations: CPT codes 97161–97164; Therapy Personal Care services: CPT code 97530; and Therapy Tests and Measurements services: CPT codes 97750, 97763 and Biofeedback: 90901, to the Medicare Telehealth Services List on a Category 1 or 2 basis. We have considered these codes over several years, in multiple cycles of annual rulemaking. In the CY 2017 final rule (81 FR 80198), we first assessed a request to add CPT codes 97110, 97112, and 97116 (the therapy codes) to the Medicare Telehealth Services List. We did not add the codes to the Medicare Telehealth Services List at the time, because there was no emergency waiver providing an exception to the requirements under section 1834(m)(4)(E) of the Act, and physical therapists, occupational therapists, and speech-language pathologists were not eligible telehealth practitioners. In the CY 2018 final rule (82 FR 53008 and 53009), we reiterated our initial assessment that the codes were not appropriate to add to the Medicare Telehealth Services List, because the majority of the therapy codes listed above are furnished over 90 percent of the time by therapy professionals who are not included on the list of distant site practitioners who can furnish telehealth services at section 1834(m)(4)(E) of the Act. We stated that we believed that adding therapy services to the Medicare Telehealth Services List could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth (82 FR 53009).

Section 3703 of Division A, Title III, Subtitle D of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, enacted March 27, 2020) amended section 1135(b)(8) of the Act to give the Secretary emergency authorities to waive or modify Medicare telehealth payment requirements under section 1834(m) of the Act during the PHE for COVID–19. Using this authority, CMS issued a set of emergency waivers that included waiving the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services. This allowed for therapy professionals to furnish telehealth services for the duration of the PHE. In the CY 2022 final rule (86 FR 65051), we reviewed another round of submissions requesting that CMS add therapy codes to the Medicare Telehealth Services List, and we again determined that these codes did not meet the Category 1 criterion for addition to the list. In the CY 2023 PFS final rule (87 FR 69451), through our review of evidence that was submitted by interested parties in support of adding these services to the Medicare Telehealth Services List on a Category 2 basis, we concluded that there was not sufficient information to determine whether all of the necessary elements of these services could be furnished remotely.

In reviewing this year's request, the evidence submission includes evidence similar to what was submitted last year, with a few new additions suggesting that some elements of the individual services may have clinical benefit when furnished via telehealth, but not resolving uncertainty about whether other elements of the services can be fully furnished remotely via telehealth. The evidence submitted also suggests that receiving therapy services via telehealth in the home may offer some practical benefits, such as use of actual stairs in therapy exercise instead of artificial stairs, or meal preparation instructions focused on available kitchen tools and equipment. However, the evidence submitted for review leaves open questions as to whether such differences in the setting of care translate to a clinical benefit that is more than minor or incidental, in typical circumstances for the typical population of beneficiaries who may receive therapy services via telehealth.

We note that for any submission, including submissions received for these therapy services, we consider all elements of a service as described by a particular HCPCS code and apply our review criteria to the specific code. While some submitted information may focus on an individual service within one specific clinical scenario, and furnished within one specific individual model of care delivery, that information may not be generalizable to the varied settings and scenarios under which the service would be typically furnished via telehealth. We reiterate that available evidence should give a reasonable degree of certainty that all elements of the service could fully and effectively be furnished by a remotely-located clinician using two-way, audio/video telecommunications technology.

Based on the evidence we reviewed, we continue to question whether the findings from therapy studies that focused on a specific clinical issue for a narrow population (for example, joint replacement of a specific joint) translate to clinical benefit for some or many of the various other clinical issues that would typically be addressed when therapists furnish therapy services via telehealth to beneficiaries. Despite the evidence, we are still uncertain as to whether all of the elements of a therapy service could typically be furnished through use of only real-time, two-way audio/video communications technology. Because we continue to have these questions, we are not proposing to add these services to the Medicare Telehealth Services List on a Category 1 or 2 basis, for the same reasons described in our CY 2018 through CY 2023 rulemaking cycles. Also, we continue to believe that adding these therapy services to the Medicare Telehealth Services List permanently would potentially generate confusion. As discussed in last year's final rule, we note that we do not have authority to expand the list of eligible Medicare telehealth practitioners to include therapists (PTs, OTs, or SLPs) after CY 2024 (87 FR 69449 through 69451). We note that the CAA, 2023, did not permanently change the list of practitioners who can furnish and bill for telehealth services; rather, the CAA, 2023, extended the current telehealth flexibilities through the end of CY 2024. That said, we are proposing to keep these therapy services on the Medicare Telehealth Services List until the end of CY 2024. We will consider any further action with regard to these codes in future rulemaking.

(5) Hospital Care, Emergency Department and Hospital

We received a request to permanently add the following CPT codes to the Medicare Telehealth Services List:

- 99221 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*)
- 99222 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the*

encounter for code selection, 55 minutes must be met or exceeded.)
- 99223 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.*)
- 99234 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)
- 99235 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.*)
- 99236 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.*)
- 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter*)
- 99239 (*Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter*)
- 99281 (*Emergency department visit for the evaluation and management of a patient that may not require the presence of a physician or other qualified health care professional*)
- 99282 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making*)
- 99283 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making*)

In the March 31, 2020 interim final rule with comment period (IFC–1) (85 FR 19234), we added the above services to the Medicare Telehealth Services List on a Category 2 basis for the duration of the PHE for COVID–19, for telehealth services with dates of service beginning March 1, 2020 through the end of the PHE (including any renewals of the PHE). When we previously considered adding these services to the Medicare Telehealth Services List, either through a public request or through our own internal review, we considered whether these services met the Category 1 or Category 2 criteria. In many cases, we reviewed requests to add these services to the Medicare Telehealth Services List on a Category 1 basis, but did not receive or identify information that allowed us to determine whether these services should be added on a Category 2 basis (CY 2017 PFS final rule, at 81 FR 80194 to 80197). We reiterate that, while we do not believe the context of the PHE for COVID–19 changes the assessment of whether these services meet the Category 1 criterion, we reassessed all of these services to determine whether they meet the criteria for inclusion on the Medicare Telehealth Services List on a Category 2 basis, in the context of the widespread presence of COVID–19 in the community. Given the exposure risks for beneficiaries, the health care work force, and the community at large, in-person interaction between professionals and patients posed an immediate potential risk that would not have been present when we previously reviewed these services in 2017. This risk created a unique circumstance where health care professionals needed to weigh the risks associated with disease exposure. For further background, in the CY 2021 final rule (FR 84506 through 84509), we explained the reasoning and considerations necessary for assigning a Category 3 status to certain codes that were added to the Medicare Telehealth Services List on a temporary basis during the PHE for COVID–19. We believe that some risk of COVID–19 remains, but also remain uncertain that available evidence gives clear support for continuing to include these services on a permanent basis under the Category 2 criterion.

As discussed in the CY 2023 PFS final rule (86 FR 69450), we believe these hospital and emergency department services may continue to be furnished safely via two-way, audio-video communication technology. We are not proposing to add these services to the list on a permanent basis at this time, but we are proposing that they would remain available on the Medicare Telehealth Services List through CY 2024.

(6) Health and Well-Being Coaching

We received a request to permanently add the following three Health and Well-being Coaching services to the Medicare Telehealth Services List:
- CPT code 0591T (*Health and well-being coaching face-to-face; individual, initial assessment*);
- CPT code 0592T (*Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes*); and
- CPT code 0593T (*Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes*).

We are not proposing to add these health and well-being coaching services to the Medicare Telehealth Services List on a permanent basis, but we are proposing to add them to the list on a temporary basis for CY 2024. The evidence included in the submitter's request notes that these codes are similar to others already available on the Medicare Telehealth Services List. Further, it appears that all elements of these services may be furnished when using two-way interactive communications technology to replace the face-to-face elements of the service. The submission, which contained two published metanalyses of literature on the clinical topic and an additional pre-publication meta-analysis that focuses on outcomes and benefits of the delivery of virtual health and well-being coaching, leaves some open questions as to whether Medicare beneficiaries would receive meaningful clinical benefit from receiving virtual-only health and well-being coaching. While the evidence is clearly evolving, it does suggest that these services could possibly meet Category 2 criteria for inclusion on the Medicare Telehealth Services List as more evidence builds. We also note that the published meta-analyses in the submission make clear that further study is necessary for a broader range of medical professionals, because conceptual articles and research and existing practice articles focus on nurses, but are sparse or silent about other general categories of medical professionals. As a reminder, we would expect that any evidence in support of adding these codes on a permanent basis should also establish clinical benefit when delivered directly by or under the supervision of the types of professionals who are Medicare telehealth practitioners. The metanalyses demonstrate that health

coaching only requires a few hours of training, and few articles submitted to CMS discuss the intensity of health coach training at all. The pre-publication metanalysis submitted for review draws less than definitive conclusions about ''potential benefits'' of health and well-being coaching and hedges that authors, ''did not find evidence of long-term benefit, possibly due to the paucity of studies examining longer-term outcomes. We caution that the certainty in the evidence for the majority of outcomes was either very low or low, primarily due to high risk of bias, heterogeneity, and impression.'' The submission and its content are sufficient to serve as a basis for adding the codes to the Medicare Telehealth Services List on a temporary basis, and we appreciate the thoughtful and transparent way the submission lays out gaps in available evidence. More time is needed to potentially close these gaps. We are not aware of any evidence to suggest that it would be inappropriate to assign a temporary status. Therefore, we are proposing to add the services to the Medicare Telehealth Services List on a temporary basis.

(7) CMS Proposal To Add New Codes to the List

In addition to the health and wellbeing coaching services submitted as requests, we are proposing to add HCPCS code GXXX5 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes*) to the Medicare Telehealth Services List. Our proposal to add HCPCS code GXXX5 to the list is contingent upon finalizing the service code description that we propose in section II.E of this proposed rule. We refer readers to the proposal in section II.E for further background. We are proposing that HCPCS code GXXX5, if finalized as proposed, receive a permanent status on the Medicare Telehealth Services List. One element of the service describes a face-to-face encounter between the clinician and beneficiary. Practitioners use clinical judgement to determine whether to complete the SDOH screening with or without direct patient interaction. Because the service description, as defined in section II.E. of this proposed rule, expects that a patient encounter may be necessary for accurate and complete screening, we believe that this element of the service describes an inherently face-to-face clinical activity. Further, the use of two-way interactive audio-video technology, as a substitute to in-person interaction, means an analogous level of care, in that using either modality would not affect the accuracy or validity of the results gathered via a standardized screening tool. As discussed in section II.E. of this proposed rule, we are proposing that this service must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. Therefore, we believe it describes a service that is sufficiently similar to services currently on the Telehealth list, specifically E/M services, and that this service be added on a permanent basis.

c. Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List

1. Overview

In CY 2020, CMS issued an array of waivers and new flexibilities for Medicare telehealth services to respond to the serious public health threats posed by the spread of COVID–19 (85 FR 19230). Our goal was to give individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of COVID–19. Recognizing the urgency of this situation and understanding that some pre-existing Medicare payment rules (including the statutory restrictions on telehealth originating sites and telehealth practitioners) needed to be modified in order to allow patients and practitioners to have access to necessary care while mitigating the risks from COVID–19, we used waiver and regulatory authorities to change certain Medicare payment rules during the PHE for COVID–19 so that physicians and other practitioners, home health and hospice providers, inpatient rehabilitation facilities, rural health clinics (RHCs), and federally qualified health centers (FQHCs) would be allowed broad flexibilities to furnish services using remote communications technology to avoid exposure risks to health care providers, patients, and the community.

In 2003, as required by section 1834(m)(4)(F)(ii), we established a process for adding or deleting services from the Medicare Telehealth Services List, which included consideration under two categories of criteria (Categories 1 and 2) (67 FR 79988). We finalized revisions to the Category 2 review criterion in the CY 2012 PFS final rule (76 FR 73102). Prior to CY 2020, CMS had not added any service to the Medicare Telehealth Services List on a temporary basis. In CY 2020, in response to the PHE for COVID–19, we revised the criteria for adding or removing services on the Medicare Telehealth Services List using a combination of emergency waiver authority and interim final rule making, so that some services would be available for the duration of the PHE on a ''temporary Category 2 basis.'' (85 FR 19234). In the CY 2021 PFS final rule (85 FR 84507), we created a third, temporary category for services included on the Medicare Telehealth Services List on a temporary basis. This new Category 3 includes many, but not all of the services that we added temporarily to the Medicare Telehealth Services List during the COVID–19 PHE. Specifically, we reviewed the services we added temporarily in response to the COVID–19 PHE and identified those for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to add the services as permanent additions to the list. Services added to the Medicare Telehealth Services List on a temporary, Category 3 basis will ultimately need to meet the Category 1 or 2 criteria in order to be added to the Medicare Telehealth Services List on a permanent basis.

Between CY 2020 and CY 2023, we added many services to the Medicare Telehealth List on a temporary basis during the PHE, and through rulemaking, we also added many of these services on a Category 3 basis. Subsequent requests and evidence submitted to CMS supported possible status changes for some of the services that are currently included on the Medicare Telehealth Services List on a Category 3 basis. However, submissions sometimes confused our use of waiver authority and regulatory flexibilities tied to the COVID–19 PHE which allow us to temporarily add services to the Medicare Telehealth Services List through the end of the PHE, with the generally applicable categories and criteria we use to consider changes to the Medicare Telehealth Services List outside the circumstances of the COVID–19 PHE. Now that the PHE for COVID–19 has ended, we intend to clarify and modify our process for making changes to the Medicare Telehealth Services List. We believe these clarifications will help address potential confusion among interested parties that submit requests for additions to the Medicare Telehealth List stemming from the distinction between services that were added to the telehealth list on the basis of COVID–19 PHE-related authorities versus services that were added temporarily on a

Category 3 basis, which does not rely on any PHE-related authority. Specifically, we created the Category 3 basis for considering changes in the Medicare Telehealth Services List as part of the process we are required to establish under section 1834(m)(4)(F)(2) for considering changes to the list in part because, with the significant expansion of remotely-furnished services in response to the COVID–19 PHE, we recognized the emergence of new data suggesting that there may be clinical benefit when certain services are delivered via telehealth, but more time is needed to develop additional evidence to support potential addition of the services on a permanent, Category 1 or Category 2 basis. Under Category 3, services are added to the list on a temporary basis to allow them to continue to be furnished via telehealth while additional evidence is developed.

In brief, throughout the COVID–19 PHE, we have reviewed all requests to add services to the Medicare Telehealth Services List and assessed whether the services in question should be added to the list, temporarily or permanently, under any of the criteria for Category 1, 2, or 3. Further, we did not reject any submissions from interested parties simply because they requested consideration under a specific category, and the submitted data did not support adding the service to the Medicare Telehealth Services List on that basis. Instead, we considered whether the service(s) should be added to the Medicare Telehealth Services List on any basis.

To avoid potential continuing confusion among those who submit requests to add services to the Medicare Telehealth Services List, and as we consider the expiration of the Medicare telehealth flexibilities extended by the CAA, 2023 through the end of CY 2024, we believe it would be beneficial to simplify our current taxonomy and multicategory approach to considering submitted requests. Further, we believe that simplification toward a binary classification approach could address the confusion we have noticed from interested parties submitting requests during the PHE. Our proposal would restore the simple binary that existed with Category 1 and 2, without displacing or disregarding the flexibility of Category 3. We propose to simply classify and consider additions to the Medicare Telehealth Services List as either permanent, or provisional.

At bottom, to consider a request to add a service to the Medicare Telehealth Services List, we need evidence that supports how the telehealth service is either clinically equivalent to a telehealth service already permanently on the list, or evidence that presents studies where findings suggest a clinical benefit sufficient for the service to remain on the list to allow time for confirmative study. We reemphasize the need for clinical evidence because that evidence serves as the principal basis for our consideration of a request; and it is sometimes missing from submissions we receive.

For example, we have received some submissions requesting the addition of services to the Medicare Telehealth Services List that are essentially framed as position papers advocating for changes in statutory requirements of section 1834(m) of the Act. While we do give such requests due consideration, the omission of clinical evidence to support the addition of a service to the Medicare Telehealth Services List using our established criteria generally leads us to conclude that the service should not be proposed for addition to the list. A fair and consistent review process for any and all submissions relies on a standard application of uniform, repeatable procedures for any individual submission, just as sound evidence should describe repeatable methods and replicable findings. Submissions that rely on narrative arguments for changes in the substantive requirements do not fit within such a fair and consistent review process. Therefore, we believe the following restatement of requirements and our review process is appropriate. We also propose some procedural refinements to the review process, specifically incorporating additional considerations into our evaluation of services, that we believe would serve to maintain scope and focus in a post-PHE context. We discuss these proposed changes in detail in the following section.

Section 1834(m)(4)(F)(ii) of the Act requires that the Secretary establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), to the definition of telehealth services for which payment can be made when furnished via telehealth under the conditions specified in section 1834(m). As specified at § 410.78(f), with the exception of a temporary policy that was limited to the PHE for COVID–19, we make changes to the list of Medicare telehealth services through the annual physician fee schedule rulemaking process. The proposed revisions to our current permanent policies, specifically our proposed assignment of a ''permanent'' or ''provisional'' status to a service and changes in status as described below, reflect the stepwise method by which we propose to consider future requests to add services to, remove services from, or change the status of, services on the Medicare Telehealth Services List, beginning for the CY 2025 Medicare Telehealth Services List, which will include submissions received no later than February 10, 2024.

2. Proposed Steps of Analysis for Services Under Consideration for Addition, or Removal, or a Change in Status, as Updates to the Medicare Telehealth Services List

Step 1. Determine whether the service is separately *payable under the PFS.*

When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, we are proposing to first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS. Under section 1834(m)(1) of the Act, Medicare telehealth services are limited to those for which payment can be made to the physician or practitioner when furnished using an interactive telecommunications system notwithstanding that the practitioner furnishing the services is not in the same location as the beneficiary; and under section 1834(m)(2)(A) of the Act, Medicare pays the same amount for a telehealth service as if the service is furnished in person. As such, Medicare telehealth services are limited to those services for which separate Medicare payment can be made under the PFS. Thus, through Step 1, we would answer the threshold question of whether a service is separately payable under the PFS. During the PHE, many submissions for addition to the Medicare Telehealth Services List advocated for CMS to change the definition of ''Medicare telehealth service'' for their specific service; some of those submissions were for services that were not separately payable under the PFS.[2] (87 FR 69449). We anticipate that Step 1, if finalized, will encourage submissions that focus on a separately payable PFS service, and that the evidence included with those submissions will show how use of interactive, two-way, audio/video telecommunications technology allows a practitioner to complete an entire, specific service, described by a HCPCS

[2] Services on the Medicare Telehealth List are used in the definition of Medicare telehealth. Some submissions may have conflated the distinction. Step 1 clarifies. Refer to the CMS website instructions for a Request for Addition at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Addition.*

code, that is equivalent to an in-person service.

We recognize that certain codes that had non-payable or bundled (not separately payable) status under the PFS before the PHE for COVID–19 were temporarily included on the Medicare Telehealth Services List to facilitate access to health care services during the PHE. However, the PHE for COVID–19 has now expired.

We believe that proposed Step 1, if finalized, would lessen the administrative burden of our telehealth services review process for both CMS and the public. We note that before gathering evidence and preparing to submit a request to add a service to the Medicare Telehealth Services List, the submitter should first check the payment status for a given service and ensure that the service (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by payment status indicators A, C, T, or R on our public use files). For a full list of all PFS payment status indicators and descriptions, see the Medicare Claims Processing Manual (IOM Pub. 100–04, chapter 23, section 30.2.2) and the Addendum for the MPFSDB File Record Layout. Researchers and others preparing submissions should also refer to the data dictionaries available at *https://resdac.org/cms-data/files/carrier-ffs/data-documentation*, to review whether the methodology and conclusions contained in supporting evidence, or a submission itself, applies an appropriate methodology to study both individual services and individuals that are representative of the Medicare population.

We further propose that, if we find that a service identified in a submission is not separately payable under the PFS, we would not conduct any further review of that service. We would identify the code submitted for consideration and explain that we are not proposing it for addition. CMS sends confirmation from *CMS_telehealthreview@cms.hhs.gov* when we receive a submission requesting addition of a service to, removal of a service from, or a change in status for a service included on, the Medicare Telehealth Services List. We are proposing to inform each submitter in the confirmation whether the submission was complete, lacking required information, or outside the scope of issues we consider under the process for considering changes in the Medicare Telehealth Services List. We note that we also expect submissions to include copies of any source material used to support assertions, which has been the longstanding direction included in our website instructions. For further background, refer to details available on our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Addition*.

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act.

If we determine at Step 1 that a service is separately payable under the PFS, we propose to apply Step 2 under which we would determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. A service is subject to the provisions of section 1834(m) of the Act when at least some elements of the service, when delivered via telehealth, are a substitute for an in-person, face-to-face encounter, and all of those face-to-face elements of the service are furnished using an interactive telecommunications system as defined in § 410.78(a)(3). The aim of this step is to determine whether the service is, in whole or in part, inherently a face-to-face service. As we discussed in the CY 2018 PFS final rule (83 FR 59483), it has long been the case that certain services that are furnished remotely using communications technology are not considered Medicare telehealth services and are not subject to the requirements of section 1834(m) of the Act. We are proposing Step 2 to emphasize the circumstances under which the criteria under section 1834(m) of the Act apply, and also highlight circumstances in which the criteria under section 1834(m) of the Act do not apply. As previously noted, section 1834(m) of the Act provides for payment to a physician or practitioner for a service furnished via an interactive telecommunications system notwithstanding that the furnishing practitioner and patient are not in the same location at the same amount that would have been paid if the service was furnished without the telecommunications system. We read this to mean that the scope of section 1834(m) of the Act is limited to services that would ordinarily be furnished with the furnishing practitioner and patient in the same location.

Our application of Step 2 remains consistent with longstanding policy. We reiterate that there is a range of services delivered using certain telecommunications technology that do not fall within the scope of Medicare telehealth services, though they are separately payable under the PFS. Such services generally include services that do not require the presence of, or involve interaction with, the patient (for example, remote interpretation of diagnostic imaging tests, and certain care management services). Other examples include virtual check-ins, e-visits, and remote patient monitoring services which involve the use of telecommunications technology to facilitate interactions between the patient and practitioner, but do not serve as a substitute for an in-person encounter, for example, to assess whether an in-person or telehealth visit is needed or to transmit health information to the practitioner.

In determining whether a service is subject to the provisions of section 1834(m) of the Act, we will consider whether one or more of the elements of the service, as described by the particular HCPCS code at issue, ordinarily involve direct, face-to-face interaction between the patient and practitioner such that the use of an interactive telecommunications system to deliver the service would be a substitute for an in-person visit. For interested parties preparing a request to add a service to the Medicare Telehealth Services List, we believe this Step 2 clarifies that a service must be inherently a face-to-face service. We believe reframing this Step 2 has the practical advantage of refining and improving consistency. We do not believe it would be appropriate to add a service to the Medicare Telehealth Services List if it is not subject to section 1834(m) of the Act. We would explain our finding in notice and comment rulemaking.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

We believe that the proposed Step 3 is fundamental to our commitment to health equity, as this step could have a beneficial impact on access to care for vulnerable populations. Step 3 is corollary to Step 2, and used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system as defined in § 410.78(a)(3). In Step 3, we consider whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and we seek information from submitters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations. The services are not equivalent when the

clinical actions, or patient interaction, would not be of similar content as an in-person visit, or could not be completed. We note that completing each element of the defined service is a different question than whether a beneficiary receives any benefit at all from the telehealth-only form of a candidate service. The practical basis for Step 3 mirrors the practical basis for proposed Step 1 and 2, which is a consistent application of review criteria. Many submissions that CMS received during the PHE lacked evidence indicating that some or all elements of a service could be completed using an interactive telecommunications system without still requiring an in-person interaction with a patient to furnish the complete service. We note that studies of patient satisfaction alone, and submissions with an excessive focus on patient satisfaction alone, present risks of bias in many ways, possibly complicating or obfuscating the question of whether it is possible, or potentially safe, to deliver an inherently face-to-face service via telehealth. Step 3 is integral to avoiding the possible unintended consequences of creating new gaps in care when telehealth is used as a substitute for in-person care.

Step 4. Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking.

The purpose of the proposed Step 4 of our analysis is to simplify and reduce the administrative burden of submission and review. For Step 4, we are proposing to consider whether the service elements of a code that we are considering for addition to, or removal from, the Medicare Telehealth Services List map to the service elements of a service that is already on the list and has a permanent status, because any code that satisfies this criterion would require no further analysis: if a code describes a service that maps to the service elements of a code that is included on the Medicare Telehealth Services List on a permanent basis, we would add the code to the Medicare Telehealth Services List on a permanent basis.

We note that section 1834(m)(4)(F)(i) of the Act defines telehealth services as professional consultations, office visits, and office psychiatry services (as identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary. Over the years, CMS has assigned Category 1 (permanent) status to services that were either included in the list of codes specified in section 1834(m)(4)(F)(i) of the Act or added as successor codes to those enumerated by statute. Successor codes are updates to or replacements for the codes listed in section 1834(m)(4)(F)(i) of the Act. Therefore, this proposed step would ensure that CMS includes successor codes on the Medicare Telehealth Services List. We note that even if a code that we are considering for addition to the Medicare Telehealth Services List is not a successor code, we would consider whether the service described in the submission is similar to professional consultations, office visits, and office psychiatry services that are already on the Medicare Telehealth Services List on a permanent basis. While we have not previously found that the elements of service we are considering for addition to the list map to the elements of a service that was previously added to the list on a permanent basis using the Category 2 criteria, we believe that it would be appropriate to apply this step 4 analysis to compare the candidate service with *any permanent code that is on the list on a permanent basis.* As such, in step 4, we propose to maintain any previous analytical determinations from Steps 1 through 3 and directly map the successor code to a code on the list that has a permanent status described in previous final rulemaking. For example, if a code currently categorized as a finalized Category 2 permanent code was replaced or revised by a successor code in a future year, CMS would ensure that these revisions did not change the Step 1–3 results and add the successor code under Step 4. For example, in a future year, if a code that would otherwise exist under the current categories as a finalized Category 2 permanent code, and was subsequently replaced or revised by a successor code, CMS would ensure any revisions did not alter results under Steps 1–3, and add the successor code using this Step 4. We further propose that if we find that the service we are considering satisfies Step 4, we would end our review and propose to add the service to the Medicare Telehealth Services List on a permanent basis in the next PFS proposed rule. When Step 4 is met, further evidence review is not necessary. If Step 4 is not met, then we propose to continue to Step 5.

Step 5. Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system.

Similar to Steps 3, 4, and 5 above, the purpose of the proposed step 5 is to simplify and reduce the administrative burden. Under proposed Step 5, we would review the evidence provided with a submission to determine the clinical benefit of a service. We would then compare the clinical benefit of that service, when provided via telehealth, to the clinical benefit of the service if it were to be furnished in person. Proposed Step 5 would continue the existing standard that we have applied when considering whether to add a code to the Medicare Telehealth Services List on a Category 2 basis. We further propose that: if there is enough evidence to suggest that further study may demonstrate that the service, when provided via telehealth, is of clinical benefit, CMS would assign the code a ''provisional'' status on the Medicare Telehealth Services List. Where the clinical benefit of a service, when provided via telehealth, is clearly analogous to the clinical benefit of the service when provided in person, CMS would assign the code ''permanent'' status on the Medicare Telehealth Services List, even if the code's service elements do not map to the service elements of a service that already has permanent status.

We remind readers that our evidentiary standard of demonstrated clinical benefit does not include minor or incidental benefits (81 FR 80194), and if finalized, our proposal would not alter or displace this longstanding requirement. We will review the evidence submitted by interested parties, and other evidence that CMS has on hand. The evidence should indicate that the service can be safely delivered using two-way interactive audio-video communications technology. Clinical practice guidelines, peer-reviewed literature, and similar materials, should illustrate specifically how the methods and findings within the material establish a foundation of support that each element of the defined, individual service described by the existing face-to-face service code has been studied in the typical setting of care, typical population of beneficiaries, and typical clinical scenarios that practitioners would encounter when furnishing the service using only interactive, two-way audio-video communications technology to complete the visit or encounter with Medicare beneficiaries. This analysis is fundamental to either of the current Category 1 or Category 2 descriptions.

General evidence may also answer the question of whether a certain

beneficiary population requiring care for a specific illness or injury may benefit from receiving a service via telehealth versus receiving no service at all, but must establish that the service is a substitute for an equivalent in-person service. Evidence should demonstrate how all elements described by the individual service code can be met when two-way, interactive audio-video communications technology is used as a complete substitute for any face-to-face interaction required between the patient and practitioner that are described in the individual code descriptor. We further remind readers that submissions reflecting practitioner services furnished to Medicare beneficiaries are helpful in our considerations.

Proposed Assignment of ''permanent'' or ''provisional'' Status to a Service and Changes in Status.

We are proposing to assign ''permanent'' or ''provisional'' status to any services for which the service elements map to the service elements of a service on the list that has a permanent status described in previous final rulemaking (see proposed step 4) or for which there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the service is furnished via telehealth by an eligible Medicare telehealth physician or practitioner (see proposed steps 5). These two designations (that is, ''permanent'' or ''provisional'') are intended to replace the Category 1–3 taxonomy that CMS currently uses. This proposed change is intended to reduce confusion regarding the status of codes on the Medicare Telehealth Services List and to simplify the outcome of our analysis. After a code receives the ''provisional'' status, as evidence generation builds, we may assign ''permanent'' status in a future year or we may remove the service from the list in the interest of patient safety based on findings from ongoing monitoring of telehealth services within CMS and informed by publicly available information. We would revisit provisional status through our regular annual submissions and rulemaking processes where a submission provides new evidence, or our claims monitoring shows anomalous activity, or as indicated by patient safety considerations. CMS would handle changes in status by revisiting the same steps 1 through 5 above.

Summary and Request for Feedback on Proposals To Update the Process of Review for Adding, Removing, or Changing the Status of Services on the Medicare Telehealth List

We note that the timeline for our proposed process to analyze submissions would remain the same. CY 2025 submissions would be due by February 10, 2024. Additionally, we would continue to address each submitted request for addition, deletion, or modification of services on the Medicare Telehealth Services List through annual notice and comment rulemaking.

As the end of the PHE for COVID–19 was uncertain at the time of last year's rule, many of the submissions for both CY 2023 and CY 2024 involved requests to change the status of services on the Medicare Telehealth Services List from temporary to permanent. In other words, many requestors asked CMS to consider changing the status of one or more services from Category 3 to Category 1 or 2. Based on the number of requests we received asking that CMS assign a different status to a given service, we believe a clarification is necessary to remind readers of the steps that we take when analyzing a given service for addition to, removal from, or a change in status on the Medicare Telehealth Services List. This proposal intends to refine our process and reduce confusion going forward.

To reiterate some of our discussion above, our proposals are consistent with the existing principles that CMS has applied to requests to add, remove, or change the status of a code during the COVID–19 PHE. When reviewing submissions during the PHE, in the absence of evidence supporting clinical benefit, but public comment expressing support for possible clinical benefit, CMS would generally accept a temporary addition to the Medicare Telehealth Services list, allowing more time for evidence generation. We anticipate that our approach would generally remain consistent with this particular point of flexibility if this proposal is finalized; a code could potentially receive provisional status on the Medicare Telehealth Services List in such a situation, with the caveat that our proposed Steps 1, 2, and 3, are thresholds for inclusion on the Medicare Telehealth Services List. If CMS finds that a service is not separately payable under the PFS (see proposed step 1) or it is not subject to section 1834(m) of the Act (see proposed Step 2), that service would not be added to the Medicare Telehealth Services List on any basis (and notice of the rejection would be provided to the submitter, as noted above). We do not intend to reject a submission based solely on the fact that the requestor did not request the appropriate basis for consideration; we would still analyze the submission based on the proposed steps, and then we would propose to add, remove, or change the status of the service, or we would explain why we were not doing so.

We are soliciting comments on our proposed analysis procedures for additions to, removals from, or changes in status for services on the Medicare Telehealth Services List.

d. Consolidation of the Categories for Services Currently on the Medicare Telehealth Services List

We are also proposing to consolidate Categories 1, 2, and 3, as proposed above, for all services that are currently on the Medicare Telehealth Services List. For CY 2024, we are proposing to redesignate any services that are currently on the Medicare Telehealth Services List on a Category 1 or 2 basis and would be on the list for CY 2024 to the proposed new ''permanent,'' category while any services currently added on a ''temporary Category 2'' or Category 3 basis would be assigned to the ''provisional'' category. We believe that redesignations in this calendar year would help ease confusion in future years, including in the event that there is subsequent legislation regarding Medicare telehealth services.

Further, for a code that receives provisional status, as evidence generation builds, we may grant the code a permanent status in a future year or remove the service from the list in the interest of patient safety based on findings from ongoing monitoring of telehealth services within CMS and informed by publicly available information. We propose not to set any specific timing for reevaluation of services added to the Medicare Telehealth Services List on a provisional basis because evidence generation may not align with a specific timeframe. Our proposal not to establish any specific timing for considering changes from provisional to permanent status would avoid a potential situation in which we must remove provisional services from the Medicare Telehealth Services List because the set period tolls, only to later find evidence demonstrating that the removed service should receive permanent status. Under our proposal, we would assign a provisional status for codes that satisfy the proposed threshold steps (1, 2, and 3), and then the evidence available leaves a ''close call'' between permanent

and provisional status. We do not assign provisional status when it is improbable that the code would ever achieve permanent status.

e. Implementation of Provisions of the CAA, 2023

(1) Overview and Background

The CAA, 2022 included several provisions that extend certain Medicare telehealth flexibilities adopted during the COVID–19 PHE for 151 days after the end of the PHE. Specifically, sections 301 through 305 of Division P, Title III, Subtitle A of the CAA, 2022 amended section 1834(m) of the Act to generally extend certain PHE-related telehealth policies for services that were on the Medicare Telehealth Services List as of the date of enactment (March 15, 2021). The CAA, 2022, temporarily removed restrictions on telehealth originating sites for those services to allow telehealth services to patients located in any site in the United States at the time of the telehealth service, including an individual's home; expanded the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists; continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established for those telehealth services during the PHE; delayed the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services to a beneficiary in their home, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and continued to provide for payment of telehealth services included on the Medicare Telehealth Services List as of the March 15, 2020, that are furnished via an audio-only telecommunications system. A full discussion of these policies available in the CY 2023 PFS final rule at 87 FR 69462.

In addition, section 309 of the CAA, 2022 authorized the Secretary to implement the amendments described above, made by sections 301 through 305, through program instruction or otherwise. In the CY 2023 PFS final rule (87 FR 69446), we finalized specific telehealth policies to conform to and align with amendments made by the CAA, 2022. In our CY 2023 PFS final rule (87 FR 69462–69464), we described how CMS would issue program instructions to implement specific requirements of the CAA, 2022. We also implemented the provisions enacted in the CAA, 2022 for a 151-day extension period of certain telehealth flexibilities (discussed previously in this proposed rule). On December 29, 2022, the President signed the CAA, 2023 into law. Section 4113 of the CAA, 2023 further extends the previously-extended PHE-related telehealth policies; it requires CMS to extend the telehealth flexibilities that were previously extended (initially for 151 days after the end of the PHE) under the CAA, 2022, through December 31, 2024.

We seek to address various telehealth policies that we finalized in the CY 2023 final rule, in light of the CAA, 2023. For example, the 151-day extension period for certain flexibilities discussed in our CY 2023 final rule (and previously in this proposed rule) no longer applies, since section 4113 of the CAA, 2023 extends these flexibilities until December 31, 2024 (the extended flexibilities include: temporary expansion of the scope of telehealth originating sites for services furnished via telehealth to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home; expansion of the definition of eligible telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists; continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established for those telehealth services during the PHE; delaying the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and continued coverage and payment of telehealth services included on the Medicare Telehealth Services List as of March 15, 2020) until December 31, 2024. Both the CAA, 2022 and CAA, 2023 have the same operative effect on the scope of Medicare telehealth services; both the CAA, 2022 and CAA, 2023 give the Secretary the authority to implement the relevant telehealth provisions outside of notice and comment rulemaking through program instruction or otherwise. We intend to implement the provisions discussed above, as enacted by the CAA, 2023.

Similar to the goals of our telehealth policies addressed in last year's final rule, for CY 2024, we again seek to retain payment stability, reduce confusion and burden, and conform to all statutory requirements without unnecessary restrictions on beneficiaries' access to telehealth care. Our discussion here does not alter payment amounts or billing rules that are in effect as of January 1, 2023, and those policies will remain in effect through December 31, 2024. Instead, it is our intent in this proposed rule to clarify that certain telehealth flexibilities that were previously extended until 151 days after the end of the PHE, by the CAA, 2022, have been extended until December 31, 2024, in accordance with the amendments made by provisions of the CAA, 2023.

(2) In-Person Requirements for Mental Health Telehealth

Section 4113(d)(1) of section FF, Title IV, Subtitle B of the CAA, 2023 amends section 1834(m)(7)(B)(i) of the Act to delay the requirement for an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and again at subsequent intervals as the Secretary determines appropriate. In light of this amendment, the in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder will again be effective on January 1, 2025. In addition, 4113(d)(2) of Section FF, Title IV, Subtitle B of the CAA, 2023 modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to similarly delay in-person visit requirements for mental health visits furnished by Rural Health Clinics and Federally Qualified Health Centers via telecommunications technology. Therefore, we propose to revise the regulatory text at § 410.78(b)(3)(xiv) and (b)(4)(iv)(D) to recognize the delay of the in-person requirements for mental health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare until January 1, 2025, rather than until the 152nd day after the end of the PHE, to conform with the CAA, 2023. See section III.B. of this proposed rule for our proposal to implement similar changes for RHC and FQHC mental health visits.

(3) Originating Site Requirements

Section 4113(a)(2) of the CAA, 2023 amends section 1834(m)(4)(C)(iii) of the Act to temporarily expand the telehealth originating sites for any service on the Medicare Telehealth Services List to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, beginning on the first day after the end of the PHE for COVID–19 through December 31, 2024. We would not issue any program

instructions or proposals to limit or modify telehealth originating sites for CY 2023 or CY 2024. The list of telehealth originating sites remains as listed in our regulation at § 410.78(b)(3).

(4) Telehealth Practitioners

Section 4113(b) of the CAA, 2023 amends section 1834(m)(4)(E) of the Act to require that qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists continue to be included as telehealth practitioners beginning on the first day after the end of the PHE for COVID–19 through December 31, 2024. Therefore, the list of telehealth practitioners remains as described in our CY 2023 final rule. We will also recognize marriage and family therapists (MFT) and mental health counselors (MHC) as telehealth practitioners, effective January 1, 2024, in accordance with amendments made by section 4121 of the CAA, 2023. That section of the CAA, 2023 amends section 1861(s)(2) of the Act by adding a new subparagraph (II) that establishes a new benefit category under Part B for marriage and family therapist services (as defined in section 1861(lll)(1)) of the Act and mental health counselor services (as defined in section 1861(lll)(3) of the Act). Further, section 4121(a)(5) of the CAA, 2023 amended section 1842(b)(18)(C) of the Act to add MFTs and MHCs to the list of practitioners to whom Medicare payment may be made for their services on a reasonable charge or fee schedule basis only on an assignment-related basis. Because the definition of practitioners in section 1834(m)(4)(E) of the Act for purposes of Medicare telehealth services includes the practitioners described in section 1842(b)(18)(C) of the Act, this provision also has the effect of adding MFTs and MHCs as practitioners who can furnish telehealth services.

We are proposing to amend § 410.78(b)(2) to add new paragraphs (xi) and (xii) to specify that a marriage and family therapist as described in proposed § 410.53 and a mental health counselor as described in proposed § 410.54 are included as distant site practitioners for purposes of furnishing telehealth services.

(5) Audio-Only Services

Section 4113(e) of Division FF, Title IV, Subtitle C of the CAA, 2023 amends section 1834(m)(9) of the Act to require that the Secretary shall continue to provide for coverage and payment of telehealth services via an audio-only communications system during the period beginning on the first day after the end of such emergency period and ending on December 31, 2024. This provision applies only to telehealth services specified on the Medicare Telehealth Services List under section 1834(m)(4)(F)(i) of the Act that are permitted to be furnished via audio-only technology as of the date of enactment of the CAA, 2023 (that is, December 29, 2022).

e. Place of Service for Medicare Telehealth Services

When a physician or practitioner submits a claim for their professional services, including claims for telehealth services, they include a Place of Service (POS) code that is used to determine whether a service is paid using the facility or non-facility rate. Under the PFS, there are two payment rates for many physicians' services: the facility rate, which applies when the service is furnished in hospital or skilled nursing facility (SNF) setting, and the non-facility rate, which applies when the service is furnished in an office or other setting. The PFS non-facility rate is the single geographically adjusted fee schedule amount paid to a physician or other practitioner for services furnished in their office or other non-facility outpatient setting. The PFS facility rate is the single, geographically adjusted amount paid to a physician or other practitioner when a service is furnished in a hospital or SNF setting where Medicare is making a separate payment for the services to the facility in addition to the payment to the billing physician or practitioner for their professional services. This separate payment to the facility (hospital or SNF), often referred to as a ''facility fee,'' is made under other payment systems and reflects the facility's costs associated with the service (clinical staff, supplies, equipment, overhead) and is paid in addition to what is paid to the professional under the PFS.

Prior to CY 2017, Medicare telehealth services were reported using the GT modifier. In the CY 2017 PFS final rule, we finalized creation of a new Place of Service (POS) code to identify services furnished as Medicare telehealth services, POS ''02'' (81 FR 80199–80201). In the CY 2022 PFS final rule, we created a new POS code ''10'' to identify Medicare telehealth services for which the patient's home is the originating site (87 FR 70110 and 70111).

In response to the PHE for COVID–19, we adopted temporary policies for POS codes and PFS payment rates applicable to Medicare telehealth services. As discussed in the March 31, 2020 IFC, (85 FR 19230), we stated that, as physician practices suddenly transitioned a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for COVID–19, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in-person. Therefore, we instructed physicians and practitioners who billed for Medicare telehealth services to report the POS code that they would have reported had the service been furnished in-person. This would allow our systems to make appropriate payment for services furnished via Medicare telehealth, which, if not for the PHE for COVID–19, would have been furnished in-person, at the same rate they would have been paid if the services were furnished in-person. In order to effectuate this change, we finalized on an interim basis (85 FR 19233) the use of the CPT telehealth modifier, modifier ''95'', for the duration of the PHE for COVID–19, which is applied to claim lines that describe services furnished via telehealth; and that the practitioner should report the POS code where the service would have occurred had it not been furnished via telehealth. This allowed telehealth services to be paid at the PFS non-facility rate.

We further noted that we were maintaining the facility payment rate for services billed using the general telehealth POS code ''02'', should practitioners choose to maintain their current billing practices for Medicare telehealth during the PHE for COVID–19. In the CY 2023 PFS final rule (87 FR 69467), we finalized that we would continue to maintain payment at the rate for a service had the service been furnished in person, and that this would allow payments to continue to be made at the non-facility based rate for Medicare telehealth services through the latter of the end of CY 2023 or the end of the calendar year in which the PHE ends.

In the CY 2023 PFS final rule (87 FR 69467), we finalized that, following the end of the end of the calendar year in which the PHE, practitioners will no longer bill claims with Modifier '95' along with the POS code that would have applied had the service been furnished in person, and telehealth claims will instead be billed with the POS indicators:

- POS ''02''—is redefined as Telehealth Provided Other than in Patient's Home (Descriptor: The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home

when receiving health services or health related services through telecommunication technology.); and

• POS ''10''—Telehealth Provided in Patient's Home (Descriptor: The location where health services and health related services are provided or received through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health related services through telecommunication technology.).

We recognize that, throughout the PHE for COVID–19, behavioral health services that otherwise would have been furnished in-person have been furnished via telehealth in the patient's home. With few exceptions, prior to the PHE for COVID–19, originating sites were limited to sites such as physician's offices and hospitals. Now that behavioral health telehealth services may be furnished in a patient's home, which would then serve as an originating site, we believe these behavioral health services are most accurately valued the way they would have been valued without the use of telecommunications technology, namely in an office setting. There was an increase in utilization of these mental health services during the PHE that has persisted throughout and after expiration of the PHE for COVID–19. It appears that practice patterns for many mental health practitioners have evolved, and they are now seeing patients in office settings, as well as via telehealth. As a result, these practitioners continue to maintain their office presence even as a significant proportion of their practice's utilization may be comprised of telehealth visits. As such, we believe their practice expenses (PEs) are more accurately reflected by the non-facility rate.

Therefore, we are proposing that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) be paid at the non-facility PFS rate. When considering certain practice situations (such as in behavioral health settings, where practitioners have been seeing greater numbers of patients via telehealth), practitioners will typically need to maintain both an in-person practice setting and a robust telehealth setting. We expect that these practitioners will be functionally maintaining all of their PEs, while furnishing services via telehealth. When valuing services, we believe that there are few differences in PE when behavioral health services are furnished to a patient at home via telehealth as opposed to services furnished in-person (that is, behavioral health settings require few supplies relative to other healthcare services). Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the PFS facility rate beginning on January 1, 2024, as we believe those services will be furnished in originating sites that were typical prior to the PHE for COVID–19, and we continue to believe that, as discussed in the CY 2017 PFS final rule (81 FR 80199 through 80201), the facility rate more accurately reflects the PE of these telehealth services; this applies to non-home originating sites such as physician's offices and hospitals. In this way, we believe we would be protecting access to mental health and other telehealth services by aligning with telehealth-related flexibilities that were extended via the CAA, 2023, as we will be more accurately recognizing the resource costs of behavioral health providers, given shifting practice models.

f. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List in the past, we have included certain restrictions on how frequently a service may be furnished via Medicare telehealth. These limitations include a limit of once every 3 days for subsequent inpatient visits, added in in the CY 2011 PFS final rule (75 FR 73317 through 73318), and once every 14 days for subsequent nursing facility (NF) visits, added in the CY 2016 final rule (80 FR 71062) furnished via Medicare telehealth and a limit of once per day for critical care consultation services; in establishing these limits, we cited concerns regarding the potential acuity of these patients. End-stage renal disease (ESRD)-related clinical assessments may be furnished via telehealth, subject to the frequency limitations in section 1881(b)(3)(B) of the Act, which provides that patients must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

In the March 31, 2020 COVID–19 IFC (85 FR 19241), we stated that as it was our assessment that there was a patient population who would otherwise not have had access to clinically appropriate in-person treatment, and we did not believe these frequency limitations were appropriate or necessary under the circumstances of the PHE. Therefore, we removed the frequency restrictions for certain subsequent inpatient visits, subsequent NF visits, and for critical care consultations furnished via Medicare telehealth for the duration the PHE for COVID–19. The frequency limitations resumed effect beginning on May 12, 2023, (upon expiration of the PHE), in accordance with the March 31, 2020 IFC. However, we stated that, pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020,[3] we were exercising enforcement discretion and will not consider these frequency limitations through December 31, 2023; and that we anticipated considering our policy further through our rulemaking process. As discussed below, we are proposing to once again remove these telehealth frequency limitations beginning CY 2024. We are proposing to remove the telehealth frequency limitations for the following codes:

1. Subsequent Inpatient Visit CPT Codes:

• 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. when using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*);

• 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. when using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*); *and*

• 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*)

2. Subsequent Nursing Facility Visit CPT Codes:

• 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward*

[3] *https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf.*

medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.);

• 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*);

• 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); and

• 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)

3. Critical Care Consultation Services: HCPCS Codes:

• G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth.*); and

• G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.*)

We are proposing to remove the frequency limitations for these codes for the duration of CY 2024, which will align with other telehealth-related flexibilities extended by the CAA, 2023. CMS is broadly assessing our telehealth regulations, in light of the way practice patterns may have changed in the roughly 3 years of the PHE for COVID–19 and, while we engage in this assessment, we believe it is reasonable to pause certain pre-pandemic restrictions, such as these frequency limitations, to allow us to gather more information. We are seeking information from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care consultation services since the expiration of the PHE.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Direct Supervision via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, are required to be furnished under specific minimum levels of supervision by a physician or practitioner. For most services furnished by auxiliary personnel incident to the services of the billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), direct supervision by a physician, PA, NP, or CNS is required (see also § 410.27(a)(1)(iv)(B)(*1*) for hospital outpatient services). Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. We have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)). Through the March 31, 2020 COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In the March 31, 2020 IFC (85 FR 19246) and in our CY 2022 PFS final rule (see 85 FR 65063), we also noted that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of Medicare telehealth services by clinical staff of physicians and other practitioners' incident to their own professional services. This is especially relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners were previously only able to bill Medicare for telehealth services under Medicare telehealth waivers that were effective during the PHE for COVID–19 (based on the emergency waiver authority established in section 1135(b)(8) of the Act), until the CAA, 2023 extended the time period during which these practitioners could bill for Medicare telehealth services through December 31, 2024. We noted that sections 1834(m)(4)(D) and (E) of the Act specify the types of clinicians who may furnish and bill for Medicare telehealth services. After December 31, 2024, the types of clinicians who may furnish and bill for Medicare telehealth services include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act. We note that this will include mental health counselors (MHCs) and marriage and family therapists (MFTs) beginning January 1, 2024.

We noted in the CY 2021 PFS final rule (85 FR 84539) that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure; this was the case during the PHE, and will continue to be the case following the PHE. Under current policy as described in the CY 2021 final rule (85 FR 84539 and 84540, after December 31, 2023, the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply. As noted in the CY 2022 PFS final rule (86 FR 65062), this means the temporary exception allowing immediate availability for direct supervision through virtual presence, which facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their professional services, will no longer apply after CY 2023.

We are concerned about an abrupt transition to our pre-PHE policy that defines direct supervision under § 410.32(b)(3)(ii) to require the physical presence of the supervising practitioner beginning after December 31, 2023, given that practitioners have established new patterns of practice during the PHE for COVID–19. In the absence of evidence that patient safety is

compromised by virtual direct supervision, we believe that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as those furnished incident-to a physician's service. We believe physicians and practitioners will need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. Recognizing these concerns, we are proposing continue to define direct supervision to permit the presence and ''immediate availability'' of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024. We believe that extending this definition of direct supervision through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. We are proposing to revise the regulatory text at § 410.32(b)(3)(ii) to state that, through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

We believe this additional time will allow us further opportunity to collect information through the coming year as we consider an appropriate more permanent approach to direct supervision policy following the PHE for COVID–19. We are soliciting comment on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Specifically, we are interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if virtual direct supervision of certain types of services is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. We are also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

One potential approach to direct supervision which we could consider for future rulemaking, could be to extend or permanently establish this virtual presence flexibility for services that are valued under the PFS based on the presumption that they are nearly always performed in entirety by auxiliary personnel. Such services would include any service wholly furnished incident to a physician or practitioner's professional service, as well as the Level I office or other outpatient evaluation and management visit for established patients and the Level I Emergency Department visit. Allowing virtual presence for direct supervision of these services may balance patient safety concerns with the interest of supporting access and preserving workforce capacity for medical professionals while considering potential quality and program integrity concerns. We are soliciting comment on this potential approach for CY 2025, as well as any other approaches by which direct supervision could occur virtually that would both protect patient access and safety, as well as quality of care and program integrity concerns following CY 2024.

(1) Supervision of Residents in Teaching Settings

In the CY 2021 PFS final rule (85 FR 84577 through 84584), we established a policy that, after the end of the PHE for COVID–19, teaching physicians may meet the requirements to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites that are located outside of an Office of Management and Budget (OMB)-defined metropolitan statistical area (MSA). We made this location distinction consistent with our longstanding interest to increase beneficiary access to Medicare-covered services in rural areas and noted the ability to expand training opportunities for residents in rural settings. For all other locations, we expressed concerns that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act. In addition, we stated concerns about patient populations that may require a teaching physician's experience and skill to recognize specialized needs or testing, and whether it is possible for the teaching physician to meet these clinical needs while having a virtual presence for the key portion of the service. For a more detailed description of our specific concerns, we refer readers to the CY 2021 PFS final rule (85 FR 84577 through 84584). At the end of the PHE for COVID–19, and as finalized in the CY 2021 PFS final rule, we intended for the teaching physician to have a physical presence during the key portion of the service personally provided by residents in order to be paid for the service under the PFS, in locations that were within a MSA. This policy applies to all services, regardless of whether the patient was co-located with the resident or only present virtually (for example, the service was furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). However, interested parties have expressed concerns regarding the requirement that the teaching physician have a physical presence with the resident when a service is furnished virtually within a MSA (that is, as a Medicare telehealth service). Some interested parties have stated that during the PHE for COVID–19, when residents provided telehealth services and the teaching physician was virtually present, the same safe and high-quality oversight was provided as when the teaching physician and resident were physically co-located. In addition, these interested parties have stated that during telehealth visits, the teaching physician was virtually present during the key and critical portions of the telehealth service, available immediately in real-time, and had access to the electronic health record. As stated in section II.D.2.a. of this proposed rule, we are concerned that an abrupt transition to our pre-PHE policy may present a barrier to access to many services, and we understand that practitioners have gained clinical experience during the PHE for COVID–19, and could identify circumstances for which the teaching physician can routinely render sufficient personal and identifiable services to the patient, with a virtual presence during the key portion of the telehealth service. Given these considerations and in alignment with the telehealth policies that were extended under the provisions of the CAA, 2023, we are proposing to allow the teaching physician to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations). This would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought, through audio/video real-time communications technology,

for all residency training locations through December 31, 2024. The virtual presence policy would continue to require real-time observation (not mere availability) by the teaching physician, and excludes audio-only technology. The documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the telehealth service, this includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology. This policy does not preclude teaching physicians from providing a greater degree of involvement in services furnished with residents, and teaching physicians should still use discretion to determine whether it is appropriate to have a virtual presence rather than in person, depending on the services being furnished and the experience of the particular residents involved.

We announced that we are exercising enforcement discretion to allow teaching physicians in all residency training sites, to be present through audio/video real-time communications technology, for purposes of billing under the PFS for services they furnish involving residents. We are exercising this enforcement discretion through December 31, 2023, as we consider our virtual presence policies for services involving teaching physicians and residents further through our rulemaking process for CY 2024. For more background we refer readers to *https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf*.

We seek comment and information to help us consider how telehealth services can be furnished in all residency training locations beyond December 31, 2024, to include what other clinical treatment situations are appropriate to permit the virtual presence of the teaching physician. Specifically, we anticipate considering various types of teaching physician services, when it is appropriate for the teaching physician and resident to be co-located, and how virtual presence could support patient safety for all patients, particularly at-risk patients. We also invite commenters to provide data or other information on how the teaching physician's virtual presence could continue to support patient safety, while meeting the clinical needs for all patients, and ensure burden reduction without creating risks to patient care or increasing opportunities for fraud.

b. Clarifications for Remote Monitoring Services

(1) Background and Overview

In recent years, we have established payment for two code families that describe certain remote monitoring services: remote physiologic monitoring (RPM) and remote therapy monitoring (RTM).

Remote Physiologic Monitoring

- 99453 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*);
- 99454 (*Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*);
- 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes*); and
- 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)*).

Remote Therapeutic Monitoring

- 98975 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); initial set-up and patient education on use of equipment*);
- 98976 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*);
- 98977 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*);
- 98978 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*);
- 98980 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes*); and
- 98981 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*)

In our CY 2018 PFS final rule, we summarized feedback solicited from a comment period aimed at informing new payment policies that would allow for separate payment for remote monitoring services (82 FR 53014). In our CY 2019 PFS final rule (83 FR 59574 to 59576), we established valuations and payment policy for the RPM code family. In our CY 2020 PFS final rule (84 FR 62697–8), we explained that the RPM code family describes chronic care RPM services that involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan and the managing of a patient under the treatment plan. (84 FR 62697). In our CY 2020 PFS final rule, we also discussed that remote monitoring codes would be designated as care management services, which means our rules for general supervision would apply (84 FR 62698). In our CY 2023 PFS final rule, in response to comments, we clarified that RTM or RPM services could be billed concurrently with Chronic Care Management (CCM), Transitional Care Management TCM, Principal Care Management (PCM), Chronic Pain Management (CPM), or Behavioral Health Integration (BHI) (86 FR 69528–69539).

We have received many questions from interested parties about billing scenarios and requests for clarifications on the appropriate use of these codes in general. We believe it is important to share with all interested parties a restatement/clarification of certain policies. We refer readers to the CY 2021 PFS final rule (85 FR 84542 to 84546) for further discussion and explanation of the basis for interim policies that expired on the last day of the PHE for COVID–19.

(2) New vs. Established Patient Requirements

In the CY 2021 PFS final rule (85 FR 84542–6), we established that, when the PHE for COVID–19 ends, we again will require that RPM services be furnished only to an established patient. Patients who received initial remote monitoring services during PHE are considered established patients for purposes of the new patient requirements that are effective after the last day of the PHE for COVID–19.

(3) Data Collection Requirements

We have received various comments and inquiries about our temporary exception to minimum data collection for remote monitoring. As discussed in our CY 2021 final rule, we are not extending beyond the end of the PHE the interim policy to permit billing for remote monitoring codes, which require data collection for at least 16 days in a 30-day period, when less than 16 of days data are collected within a given 30-day period. (85 FR 84542 through 84546). As of the end of the PHE, the 16-day monitoring requirement was reinstated. Monitoring must occur over at least 16 days of a 30-day period. We are proposing to clarify that the data collection minimums apply to existing RPM and RTM code families for CY 2024.

The following remote monitoring codes currently depend on collection of no fewer than 16 days of data in a 30-day period, as defined and specified in the code descriptions:

- 98976 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*);
- 98977 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*);
- 98978 (*Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days*);
- 98980 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes*); and
- 98981 (*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*)

We remind readers that our discussion in the CY 2021 PFS final rule addresses the interim policy on data collection minimums, and provides notice and the rationale for the data collection policy that is in effect now that the PHE for COVID–19 has ended. Remotely monitored monthly services should be reported only once during a 30-day period—and only when reasonable and necessary. As a clarification for either RPM or RTM, only one practitioner can bill CPT codes 99453 and 99454, or CPT codes 98976, 98977, 98980, and 98981, during a 30-day period, and only when at least 16 days of data have been collected on at least one medical device as defined in section 201(h) of the FFDCA.

We reiterate our analysis described in the CY 2021 PFS final rule, in which we explained that CPT code descriptor language suggests that, even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected (85 FR 84545). We refer readers to our CY 2021 PFS final rule (85 FR 84545) for additional background.

(4) Use of RPM, RTM, in Conjunction With Other Services

Practitioners may bill RPM or RTM, but not both RPM and RTM, concurrently with the following care management services: CCM/TCM/BHI, PCM, and CPM. These various codes, which describe other care management services, may be billed with RPM or RTM, for the same patient, if the time or effort is not counted twice. As specified in the CY 2023 PFS final rule, if all requirements to report each service are met, without time or effort being counted more than once, RPM or RTM (not both RPM and RTM) may be billed in conjunction with any one of CCM, TCM, BHI, PCM, or CPM codes. According to the 2023 CPT Codebook (pg. 849), CPT code 98980 (*RTM treatment management*) cannot be reported in conjunction with CPT codes 99457/99458 (*RPM treatment management*). Our intention is to allow the maximum flexibility for a given practitioner to select the appropriate mix of care management services, without creating significant issues of possible fraud, waste, and abuse associated with overbilling of these services. We continue to gain experience with each family of remote monitoring codes, and request feedback from commenters that would provide additional context that could inform us as we continue to develop and clarify our payment policies for these services.

We propose to clarify that RPM and RTM may not be billed together, so that no time is counted twice by billing for concurrent RPM and RTM services. In instances where the same patient receives RPM and RTM services, there may be multiple devices used for monitoring, and in these cases, we will to apply our existing rules, which we finalized when establishing the RPM code family, meaning that the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary (85 FR 84544 through 84545).

(5) Other Clarifications for Appropriate Billing

We have received inquiries from interested parties during public forums regarding use of remote monitoring during global periods for surgery. We are proposing to clarify that, in circumstances where an individual beneficiary may receive a procedure or surgery, and related services, which are covered under a payment for a global period, RPM services or RTM services (but not both RPM and RTM services concurrently) may be furnished separately to the beneficiary, and the practitioner would receive payment for the RTM or RPM services, separate from the global service payment, so long as other requirements for the global service and any other service during the global period are met. For an individual beneficiary who is currently receiving services during a global period, a practitioner may furnish RPM or RTM services (but not both RPM or RTM services) to the individual beneficiary, and the practitioner will receive separate payment, so long as the remote monitoring services are unrelated to the diagnosis for which the global procedure is performed, and as long as the purpose of the remote monitoring addresses an episode of care that is separate and distinct from the episode of care for the global procedure—meaning that the remote monitoring services address an underlying condition that is not linked to the global procedure or service.

We are soliciting comment on the above proposals and clarifications and request general feedback from the public that may be useful in further development of our payment policies for remote monitoring services that are separately payable under the current PFS.

c. Telephone Evaluation and Management Services

In the March 31st COVID–19 IFC (85 FR 19264 through 19265), we finalized separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. CPT codes 99441 through 99443 are telehealth services and will remain actively priced through 2024. CPT codes 98966–98968, however, describe telephone assessment and management services provided by a qualified non-physician healthcare professional, and they are not telehealth services. We are proposing to continue to assign an active payment status to CPT codes 98966 through 98968 for CY 2024 to align with telehealth-related flexibilities that were extended via the CAA, 2023, specifically section 4113(e), which permits the provision of telehealth services through audio-only telecommunications through the end of 2024.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed MEI increase for CY 2024 is 4.5 percent and is based on the expected historical percentage increase of the 2017-based MEI. For the final rule, we propose to update the MEI increase for CY 2024 based on historical data through second quarter of 2023.

Therefore, for CY 2024, the proposed payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $29.92. Table 10 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

TABLE 10: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023	3.8	$ 28.64
2024*	4.5	$ 29.92

*Reflects the most recent estimate of the CY 2024 MEI percentage increase and will be updated in the final rule based on historical data through the second quarter of 2023.

4. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology

a. Background on Outpatient Therapy Services, Diabetes Self-Management Training and Medical Nutrition Therapy

Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services, (expressly for PT services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services). Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Section 1834(k)(3) of the Act requires payment for outpatient therapy services to be made based on the PFS (via section 1848 of the Act), for all institutional providers listed at sections 1833(a)(8) and (9) of the Act. These providers include clinics, rehabilitation agencies, public health agencies, comprehensive outpatient rehabilitation agencies (CORFs), SNFs, home health agencies (HHAs) (to individuals who are not homebound), hospitals to outpatients or hospital inpatients who are entitled to benefits under part A but have exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A), and all other CORF services.

Section 1861(qq) of the Act defines Diabetes Self-Management Training (DSMT) services and authorizes CMS to regulate Medicare DSMT outpatient services. A ''certified provider'' of DSMT is further defined in section 1861(qq)(2)(A) of the Act as a physician or other individual or entity designated by the Secretary who meets certain quality requirements described in section 1861(qq)(2)(B) of the Act. In CY 2000, we finalized a standalone rule titled ''Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements.'' In that rule, we finalized that payment for outpatient DSMT would be made under the PFS (65 FR 83132). We further established that, in the case of payments made to other approved entities, such as hospital outpatient departments, ESRD facilities, and durable medical equipment suppliers, the payment would be equal to the amounts established under the PFS and made under the appropriate payment systems (65 FR 83142).

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. In the CY 2000 PFS final rule, we established that payment for MNT services furnished in the institutional setting, including hospital outpatient departments (HOPDs), would be made under the PFS, not under the hospital Outpatient Prospective Payment System (OPPS) (66 FR 55279).

During the PHE for COVID–19, outpatient therapy services, DSMT, and MNT could be furnished via a telecommunications system to beneficiaries in their homes, and bills for these services were submitted and paid either separately or as part of a bundled payment, when either personally provided by the billing practitioner or provided by institutional staff and billed for by institutions, such as HOPDs, SNFs, and HHAs. For professionals, CMS used waiver authority to expand the range of practitioners that can serve as distant site practitioners for Medicare telehealth services as described in section 1834(m)(4)(E) of the Act and § 410.78 (b)(2), as well as to waive the originating site requirements for Medicare telehealth services described in section 1834(m)(4)(C) of the Act. This allowed for outpatient therapy services to be furnished and billed by therapists in private practice, as well as for outpatient therapy services, DSMT, and MNT to be furnished via Medicare telehealth to beneficiaries in urban, as well as rural, areas, including to beneficiaries located in their homes.

When therapists (PTs, OTs and SLPs) were added as distant site telehealth practitioners using waiver authority during the PHE for COVID–19, CMS generally took the position for services furnished in HOPDs that waiver authority was needed to allow hospitals to bill for services furnished by hospital staff through communication technology to beneficiaries in their homes. CMS implemented the Hospitals Without Walls (HWW) policy that relied on waiver authority, which allowed hospitals to reclassify patients' homes as part of the hospital. HWW allowed hospitals to bill two different kinds of fees for services furnished remotely to patients in their homes: (1) hospital facility payment in association with professional services billed under the PFS; and (2) single payment for a limited number of practitioner services, when statute or other applicable rules only allow the hospital to bill for services personally provided by their staff. These services are either billed by hospitals or by professionals, there would not be separate facility and professional billing. This latter category includes outpatient therapy services, DSMT, and MNT. However, while maintaining that waiver authority was needed to allow hospital billing for these services, CMS also issued guidance instructing HOPDs to bill using modifiers consistent with those used for Medicare telehealth services. For further background, we refer readers to *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*. In the same referenced document, CMS also issued specific guidance for other institutional providers of therapy services to use modifier 95 (indicating a Medicare telehealth service), along with the specific bill types for outpatient therapy services furnished by their staff.

The CAA, 2023 extended many of the flexibilities that were available for Medicare telehealth services during the PHE for COVID–19 under emergency waiver authorities, including adding physical and occupational therapists and speech-language pathologists as distant site practitioners through the end of CY 2024. In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID–19 along with the HWW waivers. However, after reviewing input from interested parties, as well as relevant guidance, including applicable billing instructions, we are considering whether certain institutions, as the furnishing providers, can bill for certain remotely furnished services personally performed by employed practitioners.

b. Proposal To Extend Billing Flexibilities for Certain Remotely Furnished Services Through the End of CY 2024 and Comment Solicitation

While we consider how we might address this ambiguity in future rulemaking, in the interests of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff

to beneficiaries in their homes consistent with the accessibility of these services when furnished by professionals via Medicare telehealth, we are proposing to continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID–19 through the end of CY 2024. We are seeking comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. We are seeking comment as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other relevant authorities CMS might consider in future rulemaking.

For DSMT specifically, the clinical staff personally delivering the service may be a type of practitioner authorized to furnish Medicare telehealth services under section 1834(m) of the Act; but we also understand that DSMT may be provided by other types of staff. Accordingly, we noted in sub-regulatory guidance that we are exercising enforcement discretion in reviewing the telehealth eligibility status of the practitioner personally providing any part of a remotely furnished DSMT service, so long as the persons were otherwise qualified to provide the service. For more background we refer readers to *https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf*.

As we review our telehealth policies following the end of the PHE for COVID–19, and consider care delivery and beneficiary access concerns raised by practitioners and beneficiary advocates, we are broadly considering billing and payment for telehealth services in institutional settings, including when these services are furnished by practitioners who have reassigned their rights to bill under and receive payment from the Medicare program (billing rights) to an institution. We acknowledge that one such setting where this billing arrangement exists includes Critical Access Hospitals (CAHs), where a practitioner has reassigned their billing rights to the CAH, and CMS makes payment for the practitioner's services under an optional payment method, referred to as CAH method II (Pub. 100–04, Chapter 4, Section 250.2). We note that in situations when a practitioner is furnishing a telehealth service and has reassigned their billing rights to a CAH under Method II, CMS makes payment for the telehealth service at the same rate generally paid for other in-person services (100 percent of the PFS payment amount) rather than the payment amount established under the optional method as discussed in Pub. 100–04, Chapter 4, Section 250.2. We are interested in and are soliciting comment on how telehealth services furnished under CAH method II arrangements are furnished, and whether they would be most accurately characterized in the context of section 1834(m) of the Act or services of the CAH under Method II.

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and

potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of interested party reactions to our approach. We note that many commenters and interested parties have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We note that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and

magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we stated that we would seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. (83 FR 59515) We note that we also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 13 contains a list of codes and descriptors for which are proposing work RVUs for CY 2024; this includes all codes for which we received RUC recommendations by February 10, 2023. The proposed work RVUs, work time and other payment information for all CY 2024 payable codes are available on the CMS website under downloads for the CY 2024 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 13 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service.

In this proposed rule, we also note that many of the refinements listed in Table 12 of the proposed rule resulted in changes under the $0.35 threshold and were unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2024 are displayed in the CY 2024 direct PE input files, available on the CMS website under the downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the CY 2024 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2024 we received invoices for several new supply and equipment items. Tables 15 and 16 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 15 and 16 also include the number of invoices received

and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2024 are available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under paragraph (t)(2)(D) of such section, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such TC for such year. As required by the section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2024, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined previously in this proposed rule for purposes of this cap. Beginning for CY 2024, we are proposing to include the following services on the list of codes to which the OPPS cap applies: CPT codes 76883 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity*), 7X000 (*Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic*), 7X001 (*Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer*), 7X002 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only*), 7X003 (*Intraoperative epicardial cardiac (e.g.,)echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only*), 9X000 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a* second *contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure)*), 9X002 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system (List separately in addition to code for primary procedure)*), 9X003 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure)*), 9X004 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (e.g., from innominate vein) (List separately in addition to code for primary procedure)*), and 9X005 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (e.g., from the inferior vena cava) (List separately in addition*

to code for primary procedure)). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B of the Act, and thus, should be subject to the OPPS cap. We note that we previously proposed to add CPT code 76883 to the list of codes to which the OPPS cap applies in the CY 2023 PFS proposed rule, but we did not finalize its addition, noting that it was not within the statutory scope of services to which the OPPS cap applies, as it could not be split into professional and technical components at that time (87 FR 69475). Since that time, we have reinstated CPT code 76883's PC/TC split based on feedback from billing practitioners, therefore we are proposing to add it to the OPPS cap list for CY 2024.

4. Valuation of Specific Codes for CY 2024

(1) Dorsal Sacroiliac Joint Arthrodesis (CPT Code 2X000)

In September 2022, CPT deleted category III CPT code 0775T (*Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]*) and created a new Category I CPT code 2X000 (*Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device*), which was surveyed for the January 2023 RUC meeting. CPT codes 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) and 27280 (*Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed*) were added as family codes to the level of interest (LOI) form for the RUC to review. However, the specialty societies indicated that they do not consider CPT codes 27279 and 27280 as part of the same code family and requested that they not be re-reviewed by the RUC for the January 2023 meeting. The RUC agreed with the specialty societies and did not review these codes at the January 2023 meeting. The RUC stated in their recommendations for 2X000 that the clinical nature of CPT codes 27279 and 27280 is extensively disparate from 2X000 for both the surgical approach and the specialties that perform the procedures. Additionally, they stated that no substantive changes were made to CPT codes 27279 and 27280 at the September 2022 CPT panel meeting and 27279 has been reviewed by the RUC as recently as 2018.

We are proposing the RUC-recommended work RVU of 7.86 for CPT code 2X000. We are also proposing the RUC-recommended direct PE inputs without refinement.

(2) Vertebral Body Tethering (CPT Codes 2X002, 2X003, and 2X004)

At the September 2022 CPT Panel meeting, two new Category I CPT codes, 2X002 (*Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments)* and 2X003 (*Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments)* were established for thoracic tethering. In addition, another new Category I CPT code, 2X004 (*Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed*) was established for tether revision, replacement or removal. This code family was then surveyed for the January 2023 RUC meeting.

We are proposing the RUC-recommended work RVUs of 32.00 for CPT code 2X002, 35.50 for CPT code 2X003, and 36.00 for CPT code 2X004. We are also proposing the RUC-recommended direct PE inputs without refinement.

(3) Total Disc Arthroplasty (CPT Codes 22857 and 22860)

In September 2021, the CPT Editorial Panel created CPT Category I code 22860 to describe *Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)* and replace CPT Category III code 0163T (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)*), which prompted CPT codes 22860 and 22857 (*Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar*) to be surveyed for the January 2022 RUC meeting. At the January 2022 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for both CPT codes 22857 and 22860 were erroneous and that the codes should be resurveyed for the April 2022 RUC meeting. Therefore, we proposed and finalized to maintain the RUC-recommended work RVU of 27.13 for CPT code 22857 and contractor pricing for CPT code 22860 for CY 2023.

For CY 2024, we are proposing the April 2022 RUC-recommended work RVU of 27.13 for CPT code 22857, which represents no change from the current work RVU. For CPT code 22860, we disagree with the April 2022 RUC-recommended survey median work RVU of 7.50 and are proposing the survey (with experience) 25th percentile work RVU of 6.88. We note that, of the 46 ZZZ-codes with an intraservice time of 60 minutes, only four have a work RVU higher than the RUC-recommended 7.50.

We note that our proposed work RVU of 6.88 will maintain relativity with CPT codes 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*) (work RVU = 6.50, 45 minutes intra-service and 50 minutes total time), which is an anterior approach spine procedure that requires less time, and CPT code 22208 (*Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure)*) (work RVU = 9.66, 120 minutes intra-service and 135 minutes total time). As the RUC mentioned in their recommendations, these codes appropriately bracket CPT code 22860 and demonstrate relativity among similar surgical spine add-on codes. The RUC noted that their recommended work RVU of 7.50 reflects the increased intensity of spine procedures performed from an anterior approach, but we note that CPT code 22226 (*Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)*), which represents an anterior approach, and CPT code 22216 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)*), which represents a posterior or posterolateral approach, are both valued at 6.03 work RVUs and have identical IWPUTs of 0.1005. CPT codes 22216 and 22226 are ZZZ codes and have identical times as CPT code

22860, therefore, we believe the proposed survey (with experience) 25th percentile work RVU of 6.88 for CPT 22860 is more appropriate than the RUC recommended work RVU.

We are proposing the RUC-recommended direct PE inputs for both codes without refinement.

(4) Phrenic Nerve Stimulation System (CPT Codes 3X008, 3X009, 3X010, 3X011, 3X012, 3X013, 3X014, 3X015, 9X045, 9X046, 9X047, and 9X048)

In September 2022, the CPT Editorial Panel created eight new Category I CPT codes to describe insertion, repositioning, removal, and removal and replacement of a phrenic nerve stimulator system, as well as adding four additional new Category I codes to describe activation, interrogation, and programming of a phrenic nerve stimulator system. These new codes will replace thirteen Category III codes, 0424T–0436T. The twelve new Category I codes were surveyed and then reviewed for the January 2023 RUC meeting.

We are proposing the RUC-recommended work RVU for all 12 codes in the Phrenic Nerve Stimulation System family. We are proposing a work RVU of 9.50 for CPT code 3X008 (*Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]) including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation when performed*), a work RVU of 5.43 for CPT code 3X009 (*Insertion of phrenic nerve stimulator transvenous sensing lead*), a work RVU of 9.55 for CPT code 3X010 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)*), a work RVU of 5.42 for CPT code 3X011 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only),* a work RVU of 3.04 for CPT code 3X012 (*Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only*), a work RVU of 6.00 for CPT code 3X013 (*Repositioning of phrenic nerve stimulator transvenous lead(s)*), a work RVU of 6.05 for CPT code 3X014 (*Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; pulse generator*), a work RVU of 8.51 for CPT code 3X015 (*Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; transvenous stimulation or sensing lead*), a work RVU of 0.85 for CPT code 9X045 (*Therapy activation of implanted phrenic nerve stimulator system including all interrogation and programming*), a work RVU of 0.80 for CPT code 9X046 (*Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system*), a work RVU of 1.82 for CPT code 9X047 (*Interrogation and programming of implanted phrenic nerve stimulator system during a polysomnography*), and a work RVU of 0.43 for CPT code 9X048 (*Interrogation, without programming of implanted phrenic nerve stimulator system*).

We are proposing to refine the CA039 Post-operative visits (total time) for CPT code 3X014 from 36 minutes to 53 minutes to reflect the fact that this code has a Level 4 office visit and not a Level 3 office visit included in its global period; we believe that this was an unintended technical error in the RUC recommendation. We are also proposing to refine the equipment time for the exam table (EF023) equipment from 36 minutes to 53 minutes for CPT code 3X014 to conform to this proposed change in clinical labor time. For all other codes, we are proposing the direct PE inputs as recommended by the RUC without refinement.

(5) Posterior Nasal Nerve Ablation (CPT Codes 30117, 30118, 3X016, and 3X017)

In September 2022, the CPT Editorial Panel created two new endoscopy codes for ablation of the posterior nasal nerve: CPT code 3X016 (*Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve*), and CPT code 3X017 (*Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve*). In preparation for the January 2023 RUC meeting, both new posterior nasal nerve codes, 3X016 and 3X017, as well as family CPT codes 30117 and 30118, were surveyed. For CY 2024, the RUC recommended a work RVU of 3.91 for CPT code 30117, a work RVU of 9.55 for CPT code 30118, and a work RVU of 2.70 for both CPT codes 3X016 and 3X017.

We are proposing the RUC-recommended work RVU of 3.91 for CPT code 30117. We are proposing to remove the clinical labor for the CA037 (*Conduct patient communications*) activity code for CPT code 30117. This clinical labor is associated with patient communications which already take place during the CA036 (*Discharge day management*) activity code for 10-day and 90-day global procedures. We are proposing to remove this clinical labor as it would be duplicative with the communications already taking place under the CA036 activity code. We are proposing to delete supply item SB027 (*gown, staff, impervious*) because supply items SA042 (*pack, cleaning and disinfecting, endoscope*) and SA043 (*pack, cleaning, surgical instruments*) each include this same item. Supply items SA042 and SA043 are both included in the direct PE inputs for CPT Code 30117.

We disagree with the RUC-recommended work RVU of 9.55 for CPT code 30118 and are proposing a work RVU of 7.75, based on a direct crosswalk from CPT code 28298 (*Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method*) which has the same 60 minutes of intra-service time and similar total time as CPT code 30118. We believe the work RVU should be lower than the RUC recommendation of 9.55 to reflect the decrease in intra-service time from 105 minutes to 60 minutes, and the decrease in total time from 288 minutes to 211 minutes. In the case of CPT code 30118, the intra-service work time is decreasing by 43 percent and the total work time is decreasing by 27 percent but the RUC-recommended work RVU is only decreasing by 4 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in the surveyed work time should be reflected in commensurate decreases to work RVUs.

We also note that at the RUC-recommended work RVU of 9.55, the intensity of CPT code 30118 would be increasing by more than 50 percent. We disagree that there would be such a significant increase in the intensity for the procedure, as it is transitioning from inpatient to outpatient status which suggests that the intensity has remained the same or decreased over time. We also disagree that this would be the case since the intensity for CPT code 30117 is decreasing at the RUC-recommended work RVU of 3.91. Therefore, we are also proposing a work RVU of 7.75 because it maintains the current intensity of CPT code 30118 instead of resulting in an increase in intensity. The proposed work RVU of 7.75 is supported by the reference CPT codes

we compared to CPT code 30118 with the same 60 minutes of intra-service time and similar total time as CPT code 30118; reference CPT code 11970 (*Replacement of tissue expander with permanent implant*) has a work RVU of 7.49, and reference CPT code 19325 (*Breast augmentation with implant*) has a work RVU of 8.12. We believe the proposed RVU of 7.75 is a more appropriate value overall than 9.55 when compared to the range of codes with the same intra-service time and similar total time.

We are proposing to remove the clinical labor for the CA037 (*Conduct patient communications*) activity code for CPT code 30118. This clinical labor is associated with patient communications which already take place during the CA036 (*Discharge day management*) activity code for 10-day and 90-day global procedures. We are proposing to remove this clinical labor from CPT code 30118 as it would be duplicative with the communications already taking place under the CA036 activity code.

We are proposing the RUC-recommended work RVU of 2.70 for CPT codes 3X016 and 3X017. Both CPT codes 3X016 and 3X017 are endoscopic procedures; therefore, we are proposing CPT code 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*) as the endoscopic base code for both of these codes because the description of these procedures includes what is described for CPT code 31231, with the additional component of the posterior nasal nerve ablation. Both of these procedures are performed with an endoscope. CPT codes 3X016 and 3X017 are not add-on codes, and both have a 0-day global period. The endoscopic base code that we are assigning to CPT codes 3X016 and 3X017 is used in a specific type of multiple procedure payment reduction that applies to some endoscopy codes.

We are proposing to refine the RUC-recommended direct PE inputs for both CPT codes 3X016 and 3X017. For CPT code 3X016, we are refining the equipment time for the ES031 equipment (*scope video system (monitor, processor, digital capture, cart, printer, LED light)*) from 39 minutes to 32 minutes. The RUC used the CA025 (*clean scope*) time of 10 minutes instead of the CA024 (*clean room/equipment by clinical staff*) time of 3 minutes in the Scope Systems formula, when the time for CA024 is the standard; we believe that this was an unintended technical error in the RUC recommendation. We are similarly refining the equipment time for ES031 from 39 minutes to 34 minutes for CPT code 3X017.

For CPT code 3X017, we are refining the equipment time for the ES040 equipment (*PROXY endoscope, rigid, sinoscopy (0 degrees)*) from 39 minutes to 41 minutes because the RUC used 18 minutes of intra-service time for CA018 (*Assist physician or other qualified healthcare professional—directly related to physician work time (100%)*) instead of 20 minutes in the standard Scope formula. Also, for both CPT codes 3X016 and 3X017, we propose to delete supply item SB027 (*gown, staff, impervious*) because SA042 (*pack, cleaning and disinfecting, endoscope*) and SA043 (*pack, cleaning, surgical instruments*) each include this same item. Supply items SA042 and SA043 are both included in the PE inputs for CPT codes 3X016 and 3X017.

(6) Cystourethroscopy With Urethral Therapeutic Drug Delivery (CPT Code 5X000)

In September 2022, the CPT Editorial Panel replaced Category III code 0499T (*Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed*) with the new Category I CPT code 5X000 (*Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed*) to describe cystourethroscopy with mechanical urethral dilation and urethral therapeutic drug delivery. For CY 2024, the RUC recommended a work RVU of 3.10 for CPT code 5X000.

We are proposing the RUC-recommended work RVU of 3.10 for CPT code 5X000. We are also proposing the RUC-recommended direct PE inputs for CPT code 5X000 without refinement.

Since this is an endoscopic procedure, we propose CPT code 52000 (*Cystourethroscopy (separate procedure)*) as the endoscopic base code for CPT code 5X000 because the description of this procedure includes what is described for CPT code 52000 with the additional component of the urethral therapeutic drug delivery. This procedure is performed with a cystoscope. CPT code 5X000 is not an add-on code, it has a 0-day global period. The endoscopic base code that we are assigning to CPT code 5X000 is a specific type of multiple procedure payment reduction that applies to some endoscopy codes.

(7) Transcervical RF Ablation of Uterine Fibroids (CPT Code 5X005)

In September 2022, the CPT Editorial Panel deleted Category III code 0404T (*Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency*) and created a new Category I CPT code 5X005 (*Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency*) to report and describe transcervical radiofrequency ablation of uterine fibroid(s) which prompted CPT code 5X005 to be surveyed for the January 2023 RUC meeting. At the January 2023 RUC meeting, the specialty societies indicated, and the RUC agreed, that the survey results for CPT code 5X005 showed that the survey 25th percentile work RVU of 7.21 appropriately recognizes the work involved in this service.

We are proposing the RUC-recommended work RVU of 7.21 for CPT code 5X005. The RUC recommends that CPT code 5X005 be placed on the New Technology list to be re-reviewed by the RUC in 3 years to ensure correct valuation and utilization assumptions. We will revisit the valuations of CPT code 5X005 in future rulemaking as needed, based on our annual review process discussed in the background section of this proposed rule.

CPT code 5X005 includes a medium instrument pack (EQ138) as one of the practice expense inputs for this code. Since the medium instrument pack is classified as equipment, it should include time for cleaning the surgical instrument package. We noted a mistake in one of the equipment time formulas for the medium instrument pack (EQ138) which used the CA024 clean room/equipment by clinical staff time instead of the CA026 clean surgical instrument package time in the equipment formula. Therefore, we are proposing to refine the medium instrument pack equipment time from 65 minutes to 77 minutes to conform to our established policy for surgical instrument packs, otherwise we are proposing the RUC-recommended direct PE inputs without refinement.

(8) Suprachoroidal Injection (CPT Code 6X000)

In September 2022, the CPT Editorial Panel introduced category I CPT code 6X000 as a new code. CPT code 6X000 describes suprachoroidal injection, which is the injection of medication into the space between the choroid and the sclera of the eye with procedure-specific needles and an injection kit. CPT code 6X000 replaces temporary

category III CPT code 0465T (*Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)*), which was contractor priced. While there are other existing general CPT codes for injections to the eye, the AMA RUC is adding CPT code 6X000 (*Suprachoroidal space injection of pharmacologic agent (separate procedure) (Report medication separately)*) to describe a more specific service to better distinguish this procedure from the rest of the codes for eye injections in this family. CPT code 6X000 is a 000-day global code and currently, there is only one FDA-approved medication to treat macular edema associated with uveitis which is reported separately with HCPCS J-code J3299 triamcinolone acetonide (Xipere®).

We are proposing the RUC-recommended work RVU of 1.53 for CPT code 6X000. We are also proposing the RUC-recommended direct PE inputs for the code without refinement.

(9) Skull Mounted Cranial Neurostimulator (CPT Codes 619X1, 619X2, and 619X3)

In February 2022, the CPT Editorial Panel created codes 619X1, 619X2, and 619X3 to describe Skull-Mounted Cranial Neurostimulator, and these codes were surveyed for the October 2022 RUC meeting.

We are proposing the RUC-recommended work RVU of 25.75 for CPT code 619X1 (*Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)*), the RUC-recommended work RVU of 11.25 for CPT code 619X2 (*Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)*), and the RUC-recommended work RVU of 15.00 for CPT code 619X3 (*Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed*).

We are proposing the RUC-recommended direct PE inputs for CPT codes 619X1, 619X2, and 619X3 without refinement.

(10) Spinal Neurostimulator Services (CPT Codes 63685, 63688, 64XX2, 64XX3, and 64XX4)

For CPT codes 63685 (*Insertion or replacement of spinal neurostimulator pulse generator or receiver requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 63688 (*Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array*) we are proposing the RUC-recommended work RVUs of 5.19 and 4.35, respectively. We are proposing the RUC-recommended direct PE inputs for CPT codes 63685 and 63688 without refinement.

We agree with the RUC recommended contractor pricing for CPT codes 64XX2 (*Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; initial electrode array*), 64XX3 (*Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; each additional electrode array*), and 64XX4 (*Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator*); and we are proposing contractor pricing for these three codes.

(11) Neurostimulator Services-Bladder Dysfunction (CPT Codes 64590 and 64595)

For CPT codes 64590 (*Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 64595 (*Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array*) we are proposing the RUC-recommended work RVUs of 5.10 and 3.79, respectively.

We are requesting clarification on the direct PE inputs for CPT code 64590 in the non-facility setting. Specifically, we believe the RUC inadvertently proposed 56 minutes of equipment time for the EQ114 equipment (electrosurgical generator), instead of 48 minutes using the default formula for calculating equipment time. We believe that 48 minutes of equipment time for EQ114 is appropriate and matches the clinical labor time; therefore, we are proposing 48 minutes for the EQ114 equipment for CPT code 64590. We also believe that the EQ209 equipment (*programmer, neurostimulator (w-printer)*) was intended to match the same 84 minutes of equipment time listed for the EF031 power table as both were indicated to be used during the follow-up office visit. Therefore, we are proposing 84 minutes of equipment time for EQ209 for CPT code 64590.

We are proposing the remaining RUC-recommended direct PE inputs for CPT code 64590 without refinement. We are also proposing the RUC-recommended direct PE inputs for CPT code 64595 without refinement.

(12) Ocular Surface Amniotic Membrane Placement/Reconstruction (CPT Codes 65778, 65779, and 65780)

CPT code 65778 (*Placement of amniotic membrane on the ocular surface; without sutures*) was identified by the Relativity Assessment Workgroup (RAW) via the high-volume growth screen for codes with Medicare utilization over 10,000 screen. During the September 2022 RAW meeting, the specialty societies stated that CPT codes 65778, 65779 (*Placement of amniotic membrane on the ocular surface; single layer, sutured*), and 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*) would be surveyed for the January 2023 RUC meeting.

For CY 2024, we are proposing the RUC-recommended work RVUs for all three CPT codes. We are proposing a work RVU of 0.84 for CPT code 65778 (*Placement of amniotic membrane on the ocular surface; without sutures*), a work RVU of 1.75 for CPT code 65779 (*Placement of amniotic membrane on the ocular surface; single layer, sutured*), and a work RVU of 7.03 for CPT code 65780 (*Ocular surface reconstruction; amniotic membrane transplantation, multiple layers*). We are also proposing the RUC-recommended direct PE inputs for CPT codes 65778, 65779, and 65780 without refinement.

(13) Fractional Flow Reserve With CT (CPT Code 7X005)

For CY 2018, the CPT Editorial Panel established four new Category III CPT codes for fractional flow reserve derived from computed tomography (FFRCT): CPT codes 0501T–0504T. Medicare began payment for CPT code 0503T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model*) in the hospital outpatient department setting under the Outpatient Prospective Payment System (OPPS) in CY 2018 (82 FR 59284). For the PFS, we typically assign contractor pricing for Category III codes since they are temporary codes assigned to emerging technology and services. However, we

made an exception for FFRCT services and we have since been trying to understand the costs of the PE resource inputs for CPT code 0503T in the physician office setting. In the CY 2021 PFS final rule (85 FR 84630), we stated that we found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other innovative forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PE methodology; and that our recent reviews for the overall cost of CPT code 0503T had shown the costs in the physician office setting to be similar to costs reflected in payment under the OPPS (85 FR 84630). As such, we proposed to use the geometric mean costs under the OPPS as a proxy for CPT code 0503T and ultimately finalized national pricing for CPT code 0503T based on a valuation crosswalk to the technical component (TC) of CPT code 93457 in the CY 2022 PFS final rule (86 FR 65037–65042).

For CY 2024, the CPT Editorial Panel approved the replacement of Category III codes 0501T–0504T with a single new Category I code (7X005) to report non-invasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the dataset from a coronary computed tomography angiography. CPT code 7X005 (*Noninvasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional*) was reviewed at the January 2023 RUC meeting and valuation recommendations were submitted to CMS. These recommendations include a software analysis fee for FFRCT listed as a supply input which accounts for the overwhelming majority of the code's valuation.

We have long had concerns that the software algorithm in the analysis fee for CPT code 7X005 is not well accounted for in our PE methodology; however, we recognize that practitioners are incurring resource costs for purchasing the FFRCT software and its ongoing use. This was the rationale for our previous policy to use a crosswalk that reflected the overall relative resource costs for this service while we continued to consider potentially refining and updating our PE methodology. The RUC recommendations include the previously mentioned software analysis fee for FFRCT as a supply input. However, analysis fees are not well accounted for in our current PE methodology. Although we recognize that these fees are a type of cost for practitioners, we have not traditionally recognized these analysis fees as forms of direct PE in our methodology. We previously stated our belief that crosswalking the RVUs for CPT code 0503T to a code with similar resource costs (the TC for CPT code 93457) allowed CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 0503T, which would not typically be considered direct PE under our current methodology (86 FR 65038 and 65039).

We are therefore proposing to maintain the previous valuation crosswalk to the technical component of CPT code 93457 for the new FFRCT code 7X005. This new Category I code is intended as a direct replacement for Category III code 0503T, and maintaining the current crosswalk will allow the geometric mean costs under the OPPS to continue to serve as a proxy for valuation. We are specifically crosswalking the technical component of CPT code 7X005 to the technical component of CPT code 93457; we are proposing the RUC-recommended work RVU of 0.75 for the professional component of CPT code 7X005, and the global component will be comprised of their sums as usual. We also note that there was an error in the RUC's recommended equipment time for the Professional PACS Workstation (ED053), which was listed at 14.5 minutes instead of the correct 13.5 minutes based on the sum of the intraservice work time (11 minutes) plus half of the preservice work time (5 divided by 2 = 2.5 minutes).

(14) Ultrasound Guidance for Vascular Access (CPT Code 76937)

In order to specify the insertion of a peripherally inserted central venous catheter (PICC), the CPT Editorial Panel decided to create two new codes: CPT 36572 and CPT 36573, and revised CPT codes 36568, 36569 and 36584 in September of 2017. This revision of these codes created a scenario where these bundled services could be performed by a clinician that performs the procedure without imaging guidance or a radiologist that performs the procedure with imaging guidance. When this code family was surveyed again in January 2018, CPT code 76937 *(Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)* was identified as part of this code family. Since it was expected that utilization of PICC procedures would decrease once CPT code 76937 was bundled with these services, the specialty societies that perform this service proposed to review CPT code 76937 after 2 years, once more data about these services became available. CPT code 76937 was reviewed at the October 2022 RUC meeting for CY 2024.

We are proposing the RUC-recommended work RVU of 0.30 for CPT 76937. We are also proposing the RUC-recommended direct PE inputs for CPT 76937.

(15) Neuromuscular Ultrasound (CPT Codes 76881, 76882, and 76883)

Since their creation in 2011, CPT codes 76881 (*Ultrasound, complete joint (i.e., joint space and peri-articular soft-tissue structures), real-time with image documentation*) and 76882 (*Ultrasound, limited, joint or other nonvascular extremity structure(s) (e.g., joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation*) have been reviewed numerous times as New Technology/New Services by the Relativity Assessment Workgroup (RAW). In October 2016, the RAW reviewed these codes and agreed with the specialty societies that the dominant specialties providing the complete (CPT code 76881) versus the limited (CPT code 76882) ultrasound of extremity services were different than originally thought, causing variation in the typical PE inputs. The RAW recommended referral to the Practice Expense Subcommittee for review of the direct PE inputs and the CPT Editorial Panel to clarify the introductory language regarding the reference to one joint in the complete ultrasound. The PE Subcommittee reviewed the direct PE inputs for CPT codes 76881 and 76882 and adjusted the clinical staff time at the January 2017 RUC meeting, and the CPT Editorial Panel editorially revised CPT codes 76881 and 76882 to clarify the distinction between complete and limited studies and revised the introductory guidelines to clarify the reference to one joint in the complete ultrasound procedure in June 2017.

In October 2021, the CPT Editorial Panel approved the addition of CPT code 76883 (*Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image*

documentation, per extremity) for reporting real-time, complete neuromuscular ultrasound of nerves and accompanying structures throughout their anatomic course, per extremity, and the revision of CPT code 76882 to add focal evaluation. CPT codes 76881 and 76882 were identified as part of the neuromuscular ultrasound code family with CPT code 76883 and surveyed for the January 2022 RUC meeting. We reviewed these recommendations for CY 2023 and discussed our concerns with the commenters' assertions regarding typical PE inputs for CPT code 76882 in the CY 2023 PFS final rule (87 FR 69506 through 69510). Specifically, given the changes in dominant specialty for these CPT codes from 2010 to 2017, and again from 2017 to 2022, we recommended that the RUC and interested parties reconsider the PE inputs for each code based on the dominant specialty for each CPT code, based on the most recent year's Medicare claims data, and consideration of survey responses submitted to CMS in response to the CY 2023 PFS proposed rule.

The PE inputs for CPT codes 76881, 76882, and 76883 were subsequently re-reviewed at the January 2023 RUC meeting and the RUC submitted refinements to the PE inputs for CPT code 76882 only. We are proposing the RUC-recommended PE refinements for CPT code 76882 with the exception of the RUC-recommended 13.5 minutes for ED053 (Professional PACS workstation) and 23 minutes for EQ250 (ultrasound unit, portable). We note that the old intraservice time of 11 minutes was used in error when calculating the standard equipment time for ED053. Therefore, we disagree with the RUC-recommended equipment time of 13.5 minutes and are proposing 17.5 minutes for ED053, which is calculated by using the standard equipment formula for ED053 established in the CY 2017 PFS final rule (81 FR 80182) with the updated intraservice time from the CY 2023 PFS final rule ((0.5 * 5) + 15 = 17.5).

We disagree with the RUC-recommended 23 minutes of equipment time for EQ250, which includes one minute of clinical labor time for CA014 (Confirm order, protocol exam) in the highly technical equipment formula, as discussed beginning in the CY 2013 PFS final rule (77 FR 69028), in error. Therefore, the correct equipment time for EQ250 using the highly technical equipment formula would be 22 minutes. However, because the Summary of Recommendations included in the RUC recommendations did not provide a rationale for the use of the highly technical equipment formula for EQ250, we are proposing to maintain the 15 minutes of equipment time for EQ250 for CPT code 78882, which corresponds to the interservice time for this code and maintains consistency with how equipment time is allotted for EQ250 across the three codes in this family. We refer readers to the classification of highly technical equipment in the CY 2014 PFS final rule (79 FR 67639).

The RUC did not make recommendations on and we are not proposing any changes to the work RVU for CPT codes 76881, 76882, and 76883.

(16) Intraoperative Ultrasound Services (CPT Codes 76998, 7X000, 7X001, 7X002, and 7X003)

In October 2018, the Relativity Assessment Workgroup (RAW) created a screen for CMS/Other codes with Medicare utilization of 20,000 or more, and CPT code 76998 (*Ultrasonic guidance, intraoperative*) was subsequently identified as part of that screen. When CPT code 76998 was identified in the CMS/Other screen, it was noted that many specialties were represented in the Medicare claims data. Specialties representing cardiothoracic surgery, general surgery, breast surgery, urology, interventional cardiology, interventional radiology and vascular surgery jointly submitted an action plan that the RAW reviewed in October 2019. Based on the variability of intraoperative ultrasound for each specialty with differences in the typical patient and physician work, it was decided that each society would submit applications for new code(s) as needed to carve out the work currently reported with 76998 until the code was no longer needed, or until it was clear what the final dominant use of 76998 was so that a survey could be conducted.

In October 2019, the RUC referred this issue to the CPT Editorial Panel to clarify correct coding and accurately differentiate physician work, as multiple specialties currently report CPT code 76998. The CPT Editorial Panel addressed CPT code 76998 in 2020 and 2021 by adding instructional parentheticals that restrict the use of imaging guidance with vein ablation procedures and adding new codes that bundled imaging guidance for urological procedures. In May 2022, the CPT Editorial Panel created four new codes to report intraoperative cardiac ultrasound services, thus carving out most of the prior reporting of code 76998 by cardiothoracic surgeons and cardiologists.

After utilization was removed from code 76998 for vein ablation procedures, most urological procedures, cardiac procedures and intra-abdominal procedures through instructions and/or new or revised codes, it was determined that the dominant use of the code would be related to breast surgery, allowing for code 76998 to be surveyed. CPT codes 7X000 (*Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic*), 7X001 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report*), 7X002 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only*), 7X003 (*Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only*), and 76998 were surveyed by the specialty societies for the September 2022 RUC meeting.

We disagree with the RUC-recommended work RVU of 1.20 for CPT code 76998 and are proposing the total time ratio work RVU of 0.91. The RUC recommended a 7-minute total time decrease for CPT code 76998. We agree with the RUC that the intensity of CPT code 76998 (real-time during an operation) is greater than the identically-timed CPT code 76641 (*Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete*), which represents a single ultrasound session typically performed by a technician, whereas CPT code 76998 includes multiple, separate ultrasound maneuvers during a surgical procedure that require a more intense, immediate interpretation in order to direct resection of the breast tissue and ensure a thorough and complete surgical excision of the abnormal breast tissue. The proposed work RVU of 0.91 for CPT code 76998 adequately values the surgeon's 5 minutes of pre-service time, 12 minutes of intraservice time, and 5 minutes of immediate post-service time more than the same 5, 12, and 5 minutes of the technician's time for CPT code 76641, which has a work RVU of 0.73.

Additionally, the IWPUT of CPT code 76641 is appropriately less than the IWPUT of CPT code 76698, with IWPUTs of 0.0422 and 0.0572, respectively. We remind interested parties that we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, decreases in time should

be reflected in decreases to work RVUs. We disagree with the RUC-recommended maintenance of the current work RVU for CPT code 76998 for a few reasons: the RUC recommendations did not advocate for a change in intensity, and presumably some higher-intensity cardiac procedures will no longer be reported using CPT code 76998, as they can now be reported using CPT codes 7X000 through 7X003. Instead, we are proposing an appropriately lower work RVU and associated IWPUT to account for the 7-minute decrease in total time and removal of higher-intensity cardiac procedures previously reported by CPT code 76998. We note that the proposed work RVU of 0.91 for CPT code 76998 is supported by the upper brackets of CPT codes 72125 (*Computed tomography, cervical spine; without contrast material*), 72128 (*Computed tomography, thoracic spine; without contrast material*), and 72131 (*Computed tomography, lumbar spine; without contrast material*), and a lower bracket of CPT code 76641. CPT codes 72125, 72128, and 72131 represent spinal computed tomography (CT) of the cervical, thoracic, and lumbar spine, respectively.

We are proposing the RUC-recommended work RVU of 0.60 and work times of 5 minutes of pre-evaluation time, 10 minutes of intraservice time, and 3 minutes of immediate postservice time for total time of 18 minutes for CPT code 7X000. We are also proposing the RUC-recommended work times for CPT codes 7X001 and 7X002 of 10 minutes of pre-evaluation time and 20 minutes of intraservice time for both codes, and 5 and 10 minutes of immediate postservice time, for total times of 40 and 35 minutes, respectively. We are proposing the RUC-recommended work times for CPT code 7X003 with the exception of the intraservice time. We are proposing the survey median intraservice time of 15 minutes rather than the RUC-recommended 75th percentile based on the assertion in the RUC's Summary of Recommendations that the cardiologist is typically in the operating room intraoperatively with the cardiothoracic surgeon prior to and after the cardiac repair. Based on this assertion, we do not believe the cardiologist spends the same amount of time in the operating room as the cardiothoracic surgeon in CPT codes 7X001 and 7X002. Therefore, we are proposing 5 minutes of pre-evaluation time, 15 minutes of intraservice time, and 10 minutes of immediate postservice time for total time of 30 minutes for CPT code 7X003.

Due to the CPT code descriptor for CPT code 7X001, we believe that the appropriate work for this service is reflected in the combined work of CPT codes 7X002 and 7X003. We note that in the CY 2015 PFS final rule (79 FR 67669), we reviewed a similarly constructed family of codes representing interventional transesophageal echocardiography (TEE) for congenital cardiac anomalies in the same way by proposing and finalizing a work RVU for CPT code 93315 (*Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report*) equal to the combined work RVUs of CPT codes 93316 (*Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only*) and 93317 (*Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only*). We note that the Summary of Recommendations for 7X001 through 7X003 state that these intraoperative ultrasound services are expected to be very rare, as intraoperative TEE is considered the gold standard and can be performed for most patients instead, which could be reported using CPT codes 93315 through 93317. Because CPT codes 7X001 through 7X003 are an alternative to CPT codes 93315 through 93317 for congenital cardiac anomalies when intraoperative TEE is contraindicated, we believe we should maintain consistency and propose a work RVU for CPT code 7X001 that equals the combined work RVUs of CPT codes 7X002 and 7X003.

Therefore, we disagree with the RUC-recommended work RVUs of 1.90, 1.20, and 1.55 for CPT codes 7X001, 7X002, and 7X003, respectively. We are proposing a work RVU of 1.62 for CPT code 7X001 based on a crosswalk to CPT codes 73219 (*Magnetic resonance (e.g., proton) imaging, upper extremity, other than joint; with contrast material(s)*) and 78452 (*Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection*). We note that this crosswalk is strongly supported by total time ratios between CPT code 7X001 and reference CPT codes 93312 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report*) and 93315, which equal 1.66 and 1.67 respectively. We also note that this is supported by a total time ratio to the current time and work RVU for the code that cardiothoracic surgeons currently use to report this service prior to the creation of CPT code 7X001, CPT code 76998 ((40/29) * 1.20 = 1.66). Lastly, this is also supported by a total time ratio to the same CPT code 76998 after factoring in the updated total time of 22 minutes and our proposed work RVU for CPT code 76998 of 0.91 ((40/22) * 0.91 = 1.65). We note that a work RVU of 1.62 for CPT code 7X001 yields an IWPUT of 0.059, which is slightly higher than the IWPUTs of the intraoperative TEE CPT codes 93315 and 93312 that represent the complete procedure, which are 0.0532 and 0.0580, respectively.

Similar to how CPT code 7X001 is broken down into service parts by CPT code 7X002 and 7X003 to allow for multiple providers to perform different parts of the whole service done by one provider (represented by 7X001), CPT codes 93312 through 93314 and 93315 through 93317 are broken down as well. According to the RUC Database, CPT code 93316 represents placement of transesophageal probe only, typically performed by a cardiac anesthesiologist. CPT code 93313 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only*) also represents placement of transesophageal probe only, when performed by a cardiac anesthesiologist. Similarly, CPT code 7X002 represents placement and manipulation of transducer and image acquisition only, which is typically performed by a cardiothoracic surgeon according to the Summary of Recommendations.

According to the RUC Database, CPT code 93317 represents image acquisition and interpretation and report only, typically done by the cardiologist after probe placement typically performed by the cardiac anesthesiologist, represented by CPT code 93316. CPT code 93314 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only*) also represents image acquisition and interpretation and report only, typically done by the cardiologist after probe placement typically performed by the anesthesiologist, represented by CPT code 93313. Similarly, CPT code 7X003 represents interpretation and report

only, which is typically performed by a cardiologist according to the Summary of Recommendations.

Because this family is broken down into service parts in the same way CPT codes 93312 through 93314 and 93315 through 93317 are, we disagree with the RUC's recommendation to assign work RVUs for CPT codes 7X002 and 7X003 that sum to more than the aggregate work RVU for CPT code 7X001. Therefore, we are proposing a work RVU of 1.08 for CPT code 7X002 and a work RVU of 0.54 for CPT code 7X003, which sum to the proposed aggregate work RVU of 1.62 for CPT code 7X001. The proposed work RVUs for CPT code 7X002 and 7X003 were calculated by taking the aggregate work RVU of the whole service, represented by CPT code 7X001, and dividing by three based on the number of discernable service parts: probe placement and manipulation, image acquisition, and interpretation and report. Because CPT code 7X002 represents two of the three service parts performed by a cardiothoracic surgeon, we allotted ⅔ rds of the aggregated work RVU for CPT code 7X001, equaling 1.08 (1.62 * ⅔ = 1.08). Because CPT code 7X003 represents one of the three service parts performed by a cardiologist, we allotted ⅓ rd of the aggregated work RVU for CPT code 7X001, equaling 0.54 (1.62 * ⅓ = 0.54). Because the Summary of Recommendations was unclear regarding the intensity of each part of the service as broken out, we invite comments on additional ways to break down the aggregate work RVU of CPT code 7X001 to adequately account for the cardiothoracic surgeon and cardiologist's time and intensity to perform CPT codes 7X002 and 7X003, but we believe that the work RVUs should sum to no more than the aggregate work RVU for CPT code 7X001 based on similarly broken down code families that represent the more widely used intraoperative TEE procedures. The RUC did not recommend and we are not proposing any direct PE inputs for the five codes in the Intraoperative Ultrasound family.

(17) Percutaneous Coronary Interventions (CPT Code 9X070)

In September 2022, the CPT Editorial Panel created one new Category I CPT code for percutaneous coronary lithotripsy. Sixteen other percutaneous coronary intervention (PCI) codes were considered part of the code family but were ultimately not reviewed by the RUC. New add-on CPT code 9X070 was reviewed by the RUC on an interim basis for CY 2024 while the entire percutaneous coronary intervention code family was referred to the CPT Editorial Panel for restructuring for the CY 2025 cycle.

We are proposing the RUC-recommended work RVU of 2.97 for CPT code 9X070 (*Percutaneous transluminal coronary lithotripsy*). The RUC did not recommend and we are not proposing any direct PE inputs for this facility-based add-on service.

(18) Auditory Osseointegrated Device Services (CPT Codes 926X1 and 926X2)

In February 2022, the CPT Editorial Panel created CPT code 926X1 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes*) and 926X2 (*Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (list separately in addition to code for primary procedure*) for CY 2024. CPT code 926X2 serves as the add-on code for base CPT code 926X1.

We are proposing the RUC-recommended work RVU of 1.25 for CPT code 926X1 and 0.33 for CPT 926X2. We are also proposing the RUC-recommended direct PE inputs for both codes. Additionally, because audiologists provide these services, we are proposing to add CPT codes 926X1 and 926X2 to the list of audiology services that can be billed with the AB modifier, that is personally provided by audiologists without a physician/NPP referral for non-acute hearing conditions—the list for CY 2023 is available at *https://www.cms.gov/audiology-services*.

(19) Venography Services (CPT Codes 9X000, 9X002, 9X003, 9X004, and 9X005)

In February 2022, the CPT Editorial Panel created six new CPT add-on codes to describe Venography services that are performed during cardiac catheterization for congenital heart defects in the superior vena cava (SVC), the inferior vena cava (IVC), and in other congenital veins, that will be reported in conjunction with the main cardiac catheterization procedure codes (CPT codes 93593–93598). CPT codes 9X000 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure)*) and CPT codes 9X001 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; inferior vena cava (List separately in addition to code for primary procedure)*) were to replace the two more general CPT codes 75827 (*Venography, caval, superior, with serialography, radiological supervision and interpretation*) and 75825 (*Venography, caval, inferior, with serialography, radiological supervision and interpretation*). CPT code 9X001 has since been rescinded, and all the remaining new add-on codes have been clarified to state in their descriptors that they are specifically for congenital heart defects.

For CPT code 9X000 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart (List separately in addition to code for primary procedure*)), the AMA RUC proposes a work RVU of 1.20 for 10 minutes of intra-service time and total time. We are proposing the AMA RUC recommended work RVU of 1.20 with 10 minutes of intra-service time and total time for CPT code 9X000.

For CPT code 9X002 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system (List separately in addition to code for primary procedure*)), the AMA RUC proposes a work RVU of 1.13 for 10 minutes of intra-service time and total time. We note that this code has the same number of minutes as CPT code 9X000, but with a lower recommended work RVU. We are proposing the AMA RUC recommended work RVU of 1.13 with 10 minutes of intra-service time and total time for CPT code 9X002.

For CPT code 9X003 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure*)) the AMA RUC proposes a work RVU of 1.43 for 12 minutes of intra-service time and total time. We note that this code has two additional minutes than CPT code 9X000 which is 20 percent more in physician time than the 10 minutes from CPT code 9X000. We are proposing the AMA RUC recommended work RVU of 1.43 with 12 minutes of intra-service time and total time for CPT code 9X003.

For CPT code 9X004 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or*

above the heart (e.g., from innominate vein) (List separately in addition to code for primary procedure)), the AMA RUC proposes a work RVU of 2.11 for 16 minutes of intra-service time and total time. We note that this code has six additional minutes more than CPT code 9X000 (10 minutes), which is 60 percent more physician time. Although we do not imply that increases in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant increases in time within the same code family should typically be reflected in increases to work RVUs. In the case of CPT code 9X004, we believe that it would be more accurate to propose a work RVU of 1.92 to account for this increase in the surveyed work time as compared with CPT code 9X000. Therefore, we are proposing a work RVU of 1.92 along with 16 minutes of intra-service time and total time for CPT code 9X004.

For CPT code 9X005 (*Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (e.g., from the inferior vena cava) (List separately in addition to code for primary procedure*)), the AMA RUC proposes a work RVU of 2.13 for 17 minutes of intra-service time and total time. We note that this code has seven additional minutes more than CPT code 9X000 (10 minutes), which is 70 percent more physician time than CPT code 9X000. Although we do not imply that increases in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant increases in time within the same code family should typically be reflected in increases to work RVUs. In the case of CPT code 9X005, we believe that it would be more accurate to propose a work RVU of 2.04 to account for this increase in the surveyed work time as compared with CPT code 9X000. Therefore, we are proposing a work RVU of 2.04 along with 17 minutes of intra-service time and total time for CPT code 9X005.

The RUC did not recommend and we are not proposing any direct PE inputs for the five codes in the Venography Services family.

(20) General Behavioral Health Integration Care Management (CPT Code 99484, and HCPCS Code G0323)

We are proposing to refine the work RVU of both CPT code 99484 and HCPCS code G0323, as proposed (see section II.J.1.c of this proposed rule), by increasing the work RVU to 0.93 from the current 0.61 and increasing the work time to 21 minutes to match the results of the surveyed work time. For CPT code 99484 we are proposing the direct PE inputs as recommended by the RUC without refinement. We are also proposing the same PE inputs for HCPCS code G0323.

CMS created four behavioral health integration (BHI) HCPCS G-codes for CY 2017. In 2018 the codes were replaced by new CPT codes. At that time RUC specialty societies undertook a survey but the RUC did not use the survey results to establish work RVUs, and instead adopted the valuations we had finalized in 2017. For CY 2017 we finalized a work RVU of 0.61 based on a direct crosswalk from CPT code 99490 (chronic care management services) (81 FR 80351). We recognized that the services described by CPT code 99490 are distinct from those furnished under BHI, but we stated that until we have more information about how the services described by G0507 (replaced in 2018 by CPT 99484) are typically furnished, we believed valuation based on an estimate of the typical resources would be most appropriate (81 FR 80351). For CY 2022 we increased the value of CPT code 99490 from 0.61 to 1.00 (86 FR 65118).

In the CY 2023 PFS final rule (87 FR 69549) we finalized a new HCPCS code, G0323 (care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month. (*These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.*)) (See section II.J.1.c. of this proposed rule, for proposed code descriptor refinement.) We valued HCPCS code G0323 based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484, because we believed the services described by G0323 mirrored those described by CPT code 99484. We noted that we may consider changes in how this code is valued for future rulemaking.

We continue to be concerned about undervaluing care management services under the PFS given the variability of costs involved with these evolving models of care. The RUC has recommended revaluing CPT code 99484, following a survey of 63 respondents. The median survey work RVU was 1.30, and the median time was 21 minutes (all intra-service). The specialty societies recommend a value of 0.93 based on a crosswalk to code 99202. We believe the specialty societies are in a good position to understand the evolving practice models. The RUC has recommended the 25th percentile survey work RVU of 0.85. Consistent with our goals of ensuring continued and consistent access to these crucial care management services we are proposing to increase the work RVU of CPT code 99484 to 0.93. This value reflects the work RVU of CPT code 99202, which has a similar work time.

We continue to believe that the services described by HCPCS code G0323 as proposed (section II.J.1.c. of this proposed rule) closely mirror those described by CPT code 99484. As we are proposing to update the work RVU and one of the PE inputs for CPT code 99484, we continue to believe that a direct crosswalk to the work values and direct PE inputs for CPT code 99484, is an appropriate valuation of the level, time, and intensity of the services under G0323 as proposed (section II.J.1.c. of this proposed rule). As such we propose to value HCPCS code G0323, as proposed (section II.J.1.c. of this proposed rule), based on a direct crosswalk to the work values and direct PE inputs for CPT code 99484, as proposed, previously in this section.

We continue to believe that there is a systemic undervaluation of work estimates for behavioral health services. We are proposing values for CY 2024 that we believe will more accurately value the work involved in delivering behavioral health services.

(21) Advance Care Planning (CPT Codes 99497 and 99498)

In January 2022, the Relativity Assessment Workgroup reviewed CPT codes 99497 and 99498. The Workgroup determined these advance care planning services should be examined given the recent changes in evaluation and management services. The RUC recommended that CPT codes 99497 and 99498 be surveyed for physician work and practice expense for the April 2022 RUC meeting. The RUC recommended no changes in physician

time, work RVUs, or direct PE inputs for these services for CY 2024.

We are proposing the RUC-recommended work RVU of 1.50 for CPT code 99497 and 1.40 for CPT code 99498, which are the current values for these codes. We are proposing the RUC-recommended direct PE inputs for these codes without refinement.

(22) Pelvic Exam (CPT Code 9X036)

In September 2022, the CPT Editorial Panel created a new CPT code for reporting a pelvic exam—CPT code 9X036. The specialty societies noted that reimbursement for the work would be captured with the problem-oriented E/M code billed for the visit. The CPT Editorial Panel agreed, thus the new code is a practice expense only code that captures the direct practice expenses associated with performing a pelvic exam in the non-facility setting. CPT code 9X036 (*Pelvic Exam*) captures the 4 minutes of clinical staff time associated with chaperoning a pelvic exam.

We are proposing the RUC-recommended direct-PE inputs for CPT code 9X036 without refinement. As a PE-only service, the RUC did not recommend and we are not proposing a work RVU for this code.

(23) Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (CPT Codes 9X034 and 9X035)

In September 2022, the CPT Editorial Panel created two time-based add-on Category I CPT codes 9X034 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes*) and 9X035 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes*). CPT codes 9X034 and 9X035 were surveyed for the January 2023 RUC meeting. While reviewing the survey data, it was noted by specialty societies that the instructions were not sufficient as the survey data reflected time estimates that exceeded the time specified in the new time-based code descriptors. The RUC has stated that the survey results for both CPT codes 9X034 and 9X035 are inaccurate and that the codes should be resurveyed for 2025. Therefore, the RUC recommended contractor pricing for CPT codes 9X034 and 9X035 and that they be referred to the CPT Editorial Panel for revision.

We are proposing to contractor price CPT codes 9X034 and 9X035 for CY 2024.

(24) Hyperbaric Oxygen Under Pressure (HCPCS Code G0277)

In 2015, CMS created HCPCS code G0277 (*Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval*) to describe direct practice expense inputs associated with CPT code 99183 (*Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session*) (consistent with the Medicare Hospital Outpatient Prospective Payment System coding mechanism). At the September 2022 Relativity Assessment Workgroup meeting, HCPCS code G0277 was identified as a high-volume growth code with Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2015 through 2022, and was reviewed at the January 2023 RUC meeting. Hyperbaric oxygen therapy is typically administered to one patient in one hyperbaric chamber for two hours. Two hours is typical, and all inputs are prorated for four units being performed (each 30 minutes, totaling 2 hours). All medical supply and time inputs have been divided into quarters.

There has been a change in the dominant specialty providing this service, which is now primarily performed by family medicine. There has also been a change in clinical staff type, and it is now typical for a single staff person to perform all activities (RN/Respiratory Therapist) as opposed to two staff (an RN/LPN/MA and an RN/respiratory therapist). This is primarily due to a 2016 change by the National Board of Diving and Hyperbaric Medical Technology to no longer allow certified nursing assistants and certified medical assistants to be eligible to take the certified hyperbaric technologist examination. The PE Subcommittee agreed with the specialty societies to update the clinical staff type to reflect solely L047C *RN/Respiratory Therapist.* We agree with the specialties that the intra-service time is now more appropriately labeled as clinical activity CA021 (*Perform procedure/service—NOT directly related to physician work time*) as opposed to CA018 due to the change in clinical staff type.

We are proposing to refine the clinical labor time for the CA013 activity (*Prepare room, equipment, and supplies*) from 1.5 minutes to 0.5 minutes, as well as the clinical labor time for the CA016 activity (*Prepare, set-up and start IV, initial positioning and monitoring of patient*) from 1 minute to 0.5 minutes to align with the 2-minute standard for these clinical activities. We arrived at these refinements by dividing the standard 2-minutes of clinical labor times for CA013 and CA016 by four to account for all inputs being prorated for four units being performed for one typical two-hour session. CA013 and CA016 would each be 0.5 minutes per 30-minute interval, which amounts to the standard 2 minutes for these clinical activities when four units are billed for the typical two-hour session. The RUC recommends 30 minutes for clinical labor activity CA021 (*Perform procedure/service—Not directly related to physician work time (intra-service time)* based on a flawed assumption that the current 15 minutes for CA021 accounts for two patients receiving treatment at the same time. We note that it has been standard for one patient to receive treatment at a time and the current 15 minutes for CA021 is based on a time ratio to the CY 2015 RUC-recommended direct PE inputs for CPT code 99183; therefore, we disagree with this RUC recommendation and are proposing to refine the recommended intra-service CA021 clinical labor time to maintain the current 15 minutes. This is to reflect the 2015 PFS final rule where ''we used the RUC recommended direct PE inputs for 99183 and adjusted them to align with the 30 minute treatment interval'' (79 FR 67677). Each PE input is prorated for four units of G0277 being provided in one typical two-hour session. Since CPT code 99183 (*Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session*) is a 120-minute code with 60-minute intra-service time, all PE inputs in HCPCS code G0277 are prorated for four units being performed.

To conform to these changes in clinical labor time, we are also proposing to refine the equipment time for the EQ362 (*HBOT air break breathing apparatus demand system (hoses, masks, penetrator, and demand valve*)) and EQ131 (*hyperbaric chamber*) equipment items from the recommended 39.75 minutes to 23.25 minutes. This is a result of the 15-minute intra-service time, as opposed to the RUC recommendation of 30 minutes of intra-service time.

(25) Remote Interrogation Device Evaluation—Cardiovascular (HCPCS Code G2066, and CPT Codes 93297, and 93298)

CPT code 93299 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisitions(s),* receipt of transmissions and technician review, technical support and distribution of results) was

meant to serve as a catch-all for both base CPT codes 93297 and 93298, which are work-only codes. However, the CPT Editorial Panel determined that CPT code 93299 was no longer necessary if CPT codes 93297 and 93298 were assigned direct PE inputs and therefore recommended CMS to delete CPT code 93299 at the beginning of CY 2020 under the assumption that CPT codes 93297 and 93298 would be assigned direct PE inputs. Since CMS did not agree with the recommended values, CMS decided to not allocate direct PE inputs for CPT codes 93297 or 93298 and instead created contractor priced HCPCS code G2066 for CY 2020 to ensure these services could still be furnished that were previously described under 93299 (84 FR 62777–62778). Since the publication of the CY 2020 PFS Final Rule, HCPCS code G2066 has remained contractor priced and CPT codes 93297 and 93298 remain as work-only codes. CMS continues to work with MACs and interested parties to address a lot of the payment concerns surrounding G2066 such as discrepancies in payment between jurisdictions. However, interested parties have indicated that a long-term solution is needed from CMS in order to help establish payment stability for these services.

Therefore, for CY 2024, we are proposing to delete HCPCS code G2066 and propose the RUC-recommended direct PE inputs for CPT codes 93297 and 93298. Since CPT code 93298 is most commonly billed with G2066, the RUC recommended the same inputs for CPT code 93298 and HCPCS code G2066 in the event that no change would be made for HCPCS code G2066. Since CMS does agree with the RUC recommended values, we are proposing to delete HCPCS code G2066 altogether and establish direct PE-inputs for CPT codes 93297 and 93298 based on the RUC recommendations.

The RUC did not make recommendations on and we are not proposing any changes to the work RVUs for CPT codes 93297 and 93298.

(26) Payment for Caregiver Training Services

a. Background

In CY 2022, we received AMA RUC recommendations for a new code family of two codes (CPT code 96202 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes*) and CPT code 96203 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service*)) that describe group caregiver training services for patient behavior management/modification (without the patient in attendance). In CY 2023 we received AMA RUC recommendations for a family of three new caregiver training codes (CPT codes 9X015 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), and add-on code, CPT code 9X016 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015)*), and 9X017 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers*).

Historically, we have taken the position that codes describing services furnished to other individuals without the patient's presence are not covered services. As we noted in the CY 2023 PFS final rule (87 FR 69521), we have explained in previous rulemaking that we read section 1862(a)(1)(A) of the Act to limit Medicare coverage and payment to items and services that are reasonable and necessary for the diagnosis and treatment of an individual Medicare patient's illness or injury or that improve the functioning of an individual Medicare patient's malformed body member. For example, in the CY 2013 PFS final rule (77 FR 68979), when discussing payment for the non-face-to-face care management services that are part of E/M services, we stated that Medicare does not pay for services furnished to parties other than the patient. We listed, as an example, communication with caregivers. Because the codes for caregiver behavior management training describe services furnished exclusively to caregivers rather than to the individual Medicare patient, we indicated that we did not review the RUC-recommended valuation of these codes or propose to establish RVUs for these codes for purposes of PFS payment. While we did not establish payment for the new caregiver behavior management training codes in the CY 2023 PFS final rule, we indicated that we believed there could be circumstances where separate payment for such services may be appropriate. We stated that we would continue to consider the status of these and similar services in rulemaking for CY 2024 (87 FR 69522 through 69523). We specifically requested public comment on how a patient may benefit in medical circumstances when a caregiver is trained to effectively modify the patient's behavior, how current Medicare policies regarding these caregiver training services (CTS) can impact a patient's health, and how the services described by these codes might currently be bundled into existing Medicare-covered services. (87 FR 69521). Public comments were generally in favor of CMS making payment for these codes, stating that there is extensive empirical support for training parents/guardians/caregivers in behavior management/modification as a component of the standard of care for the treatment of certain health-related behavior issues and that this training promotes improved outcomes. Commenters also noted that there are several CPT codes paid under the PFS that describe services that do not include direct contact with the patient but are still considered integral to the patient's care, including, for example, separately billable care management services, interprofessional consultations, and caregiver-focused health risk assessment instrument (*e.g.,* depression inventory) for the benefit of the patient. In response to public comments, we acknowledged the important role caregivers could have in a patient's overall care.

As indicated in the CY 2023 PFS final rule, we have continued to consider whether the caregiver behavior management training and similar caregiver training services could be considered to fall within the scope of services that are reasonable and necessary under section 1862(a)(1)(A) of the Act, in alignment with the principles of the recent Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers (*https://*

www.whitehouse.gov/briefing-room/presidential-actions/2023/04/18/executive-order-on-increasing-access-to-high-quality-care-and-supporting-caregivers/) and as part of a HHS level review of our payment policies to identify opportunities to better account for patient-centered care (*https://acl.gov/programs/support-caregivers/raise-family-caregiving-advisory-council*), changes in medical practice that have led to more care coordination and team-based care, and to promote equitable access to reasonable and necessary medical services. We also believe it is important for practitioners furnishing patient centered care to use various effective communication techniques when providing patient centered care, in alignment with requirements under section 1557 of the Affordable Care Act. We believe that, in certain circumstances, caregivers can play a key role in developing and carrying out the treatment plan or, as applicable to physical, occupational, or speech-language therapy, the therapy plan of care (collectively referred to in this discussion as the ''treatment plan'') established for the patient by the treating practitioner (which for purposes of this discussion could include a physician; nonphysician practitioner such as a nurse practitioner, physician assistant, clinical nurse specialist, clinical psychologist; or a physical therapist, occupational therapist, or speech-language pathologist). In this context, we believe Caregiver Training Services (CTS) could be reasonable and necessary to treat the patient's illness or injury as required under section 1862(a)(1)(A) of the Act. We have had the opportunity to consider the best approach to establishing separate payment for the services described by the caregiver training codes, especially as it relates to a practitioner who is treating a patient and expending resources to train a caregiver who is assisting or acting as a proxy for the patient. However, we continue to explore these issues and would appreciate public comments on all aspects of the CTS proposals.

In this proposed rule for CY 2024, we include a proposed definition of ''caregiver'' for purposes of CTS, discuss the circumstances under which patients may benefit from care involving caregivers, and propose that CTS may meet the conditions for Medicare payment when treating practitioners identify a need to involve and train caregivers to assist the patient in carrying out a treatment plan. We also propose values for each of the CTS codes.

(1) Definition of a Caregiver

In our ongoing education and outreach work on the use of caregivers in assisting patients, we have broadly defined a caregiver as a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition (*https://www.cms.gov/outreach-and-education/outreach/partnerships/caregiver#:~:text=Caregivers%20are%20broadly%20defined%20as,chronic%20illness%20or%20disabling%20condition*). Further, in the context of our proposals for CTS services, we believe a caregiver is an individual who is assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling); involved on an episodic, daily, or occasional basis in managing a patient's complex health care and assistive technology activities at home; and helping to navigate the patient's transitions between care settings. For purposes of CTS, we also are including a guardian in this definition when warranted. For CTS, when we say ''caregiver'' we are also referring to guardians who for purposes of CTS, are the caregiver for minor children or other individuals who are not legally independent. In these circumstances, a caregiver is a layperson assisting the patient in carrying out a treatment plan that is established for the patient by the treating physician or practitioner and assists the patient with aspects of their care, including interventions or other activities directly related to a treatment plan established for the patient to address a diagnosed illness or injury. In this context, caregivers would be trained by the treating practitioner in strategies and specific activities that improve symptoms, functioning, and adherence to treatment related to the patient's primary clinical diagnoses. Caregiver understanding and competence in assisting and implementing these interventions and activities from the treating practitioner is critical for patients with functional limitations resulting from various conditions.

(2) Patients Who Benefit From Care Involving Caregivers

We believe that a patient-centered treatment plan should appropriately account for clinical circumstances where the treating practitioner believes the involvement of a caregiver is necessary to ensure a successful outcome for the patient and where, as appropriate, the patient agrees to caregiver involvement. There may be clinical circumstances when it might be appropriate for the physician or practitioner to directly involve the caregiver in developing and carrying out a treatment plan. Such clinical circumstances could include various physical and behavioral health conditions and circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. Conditions include but are not limited to, stroke, traumatic brain injury (TBI), various forms of dementia, autism spectrum disorders, individuals with other intellectual or cognitive disabilities, physical mobility limitations, or necessary use of assisted devices or mobility aids. The previously mentioned clinical scenarios are examples of circumstances under which CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan. For example, patients with dementia, autism spectrum disorder, or individuals with other intellectual or cognitive disabilities, may require assistance with challenging behaviors in order to carry out a treatment plan, patients with mobility issues may need help with safe transfers in the home to avoid post-operative complications, patients with persistent delirium may require guidance with medication management, patients with certain degenerative conditions or those recovering from stroke may need assistance with feeding or swallowing. Separate from medical circumstances noted previously in this section above, we also seek to avoid potentially duplicative payment. We would not expect the caregiver population receiving these services on behalf of the patient to also receive CTS on behalf of the patient under another Medicare benefit category or Federal program. Also, we note that when Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. Based on the specificity of the coding for our proposal, we do not expect that CTS will neatly overlap with any other coverage for patients who are dually eligible for Medicare and Medicaid. However, we are seeking public comment regarding whether States typically cover services similar to CTS under their Medicaid programs, and whether such coverage would be duplicative of the CTS service codes. We are seeking comment on this issue and whether payment is currently available for CTS through other Federal or other programs.

(3) Reasonable and Necessary CTS

We believe CTS could be reasonable and necessary when furnished based on an established individualized, patient-centered treatment plan or therapy plan of care accounting for the patient's specific medical needs, including, but not limited to, the examples specified previously in this proposed rule.

As provided in the code descriptors, treating practitioners may train caregivers in a group setting with other caregivers who are involved in care for patients with similar needs for assistance to carry out a treatment plan. Training for all of the caregivers for the patient could occur simultaneously, and the applicable CTS codes (CPT code 96202, 96203, and 9X017) would be billed once per beneficiary. We are seeking comment on this issue. We also seek comment on whether payment is currently available for CTS through other Federal or other programs. We are considering whether CTS would be reasonable and necessary when furnished to caregivers in more than one single session, or to (presumably the same) caregivers by the same practitioner for the same patient more than once per year and are seeking comment on this. We want to note that the treating physician or NPP may provide training to more than one caregiver for a single patient.

(4) Proposals

For CY 2024, we propose to establish an active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) and CPT codes 9X015, 9X016, and 9X017 (caregiver training services under a therapy plan of care established by a PT, OT, SLP). These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. As discussed previously in this section, we believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example, when the patient cannot follow through with the treatment plan for themselves (see examples previously mentioned in this section under ''Patients Who Benefit from Care Involving Caregivers'').

We are seeking public comment on this definition of 'caregiver' for purposes of CTS and are interested if there are any additional elements of a caregiver that we should consider incorporating in this proposed CTS caregiver definition. We think that our proposed definition would allow for holistic care of the patient with those who know and understand the patient, their condition, and their environment.

We propose that payment may be made for CTS services when the treating practitioner identifies a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered treatment plan. We further propose that because CTS services are furnished outside the patient's presence, the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS. We further propose that the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS must be documented in the patient's medical record.

We are proposing to require the full 60 minutes of time to be performed in order to report CPT code 96202. The add on code, CPT code 96203, may be reported once 75 minutes of total time is performed. We are interested in and seeking comment on how the clinician and caregiver interactions would typically occur, including when the practitioner is dealing with multiple caregivers and how often these services would be billed considering the established treatment plan involving caregivers for the typical patient.

We are soliciting public comment on each of our proposals for CTS.

b. Coding

(1) Behavior Management/Modification Training for Guardians/Caregivers of Patients With a Mental or Physical Health Diagnosis (CPT Codes 96202 and 96203)

CPT code 96202 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes*) and its add-on code, CPT code 96203 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service*)), were two new codes created by the CPT Editorial Panel during its February 2021 meeting. The two codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group behavior management/modification training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the sessions focus on interventions aimed at effectuating the practitioner's treatment plan through addressing challenging behaviors and other behaviors that may pose a risk to the person, and/or others. According to the Summary of Recommendations (which was submitted by the AMA RUC with the valuation of this code), during the face-to-face service time, caregivers are taught how to structure the patient's environment to support and reinforce desired patient behaviors, to reduce the negative impacts of the patient's diagnosis on patient's daily life, and to develop highly structured technical skills to manage the patient's challenging behavior.

Behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each behavior should be clearly identified and documented in the treatment plan, and the caregiver should be trained in positive behavior management strategies.

(a) Valuation

The RUC recommended the survey median work value for both CPT codes 96202 and 96203. Three specialty societies sent surveys to a random sample of a subset of their members. Based on survey results and after discussion, the RUC recommended a work RVU of 0.43 for a specific patient who is represented in the group session being billed for CPT code 96202. The RUC noted that this recommendation is based upon a median group size of six caregivers and includes 10 minutes pre-time, 60 minutes intra-time, and 20

minutes post-time for a total time of 90 minutes. For CPT code 96203, the 15-minute add on code, the RUC recommended a work RVU of 0.12, which is also based upon a median group size of six. We are proposing the RUC-recommended work RVU of 0.43 for CPT code 96202 and the RUC-recommended work RVU of 0.12 for CPT code 96203. We are also proposing the RUC-recommended direct PE inputs for these codes.

Finally, we note that the RUC recommendation included information suggesting that the RUC intends to review the valuation of these services again soon.

(2) Caregiver Training in Strategies and Techniques To Facilitate the Patient's Functional Performance (CPT Codes 9X015, 9X016, and 9X017)

CPT codes 9X015 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), and add-on code, CPT code 9X016 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015)*), and 9X017 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers*) are new codes created by the CPT Editorial Panel during its October 2022 meeting. The three codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing individual or group training to caregivers of patients. Although the patient does not attend the trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's ability to successfully perform activities of daily living (ADL's). Activities of daily living generally include ambulating, feeding, dressing, personal hygiene, continence, and toileting.

During the face-to-face service time, caregivers are taught by the treating practitioner how to facilitate the patient's activities of daily living, transfers, mobility, communication, and problem-solving to reduce the negative impacts of the patient's diagnosis on the patient's daily life and assist the patient in carrying out a treatment plan. These specific services are reasonable and necessary when treating practitioners identify a need to involve and train caregivers to assist the patient in carrying out a treatment plan. As part of an individualized plan of care, the caregiver is trained in skills to assist the patient in completing daily life activities. These trainings to the caregiver include the development of skills such as safe activity completion, problem solving, environmental adaptation, training in use of equipment or assistive devices, or interventions focusing on motor, process, and communication skills.

(a) Valuation

The RUC recommended work values for CPT codes 9X015, 9X016, and 9X017 based on the survey median values and the key reference CPT codes 97535 and 97130. The surveyed codes fall appropriately between these key reference services compared to the work RVU, total time, and related intensity of each service. Three specialty societies sent surveys to a random sample of a subset of their members. Based upon survey results and after discussion, the RUC recommended a work RVU 1.00 for CPT code 9X015, a work RVU of 0.54 for 9X016, and a work RVU of 0.23 per specific patient represented in the group service being billed for CPT code 9X017.

We are proposing the RUC-recommended work RVU 1.00 for CPT code 9X015, the RUC-recommended work RVU of 0.54 for 9X016, and the RUC-recommended work RVU of 0.23 per identified patient service for CPT code 9X017. The RUC noted that the recommendation for 9X017 is based on a median group size of five caregivers. We are also proposing the RUC-recommended direct PE inputs for these codes.

Finally, we note that the RUC recommendation included information suggesting that the RUC intends to review the valuation of these services again soon. We are proposing to designate 9X015, 9X016, and 9X017 as ''sometimes therapy''. This means that the services of these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care, that is where the services are not integral to a therapy plan of care, they can be furnished under a treatment plan by physicians and NPPs.

We are proposing to accept RUC recommendations as stated previously in this section for these codes.

(27) Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

a. Background

In recent years, we have sought to recognize significant changes in health care practice and been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment for care management/coordination and primary care services under the PFS. See, for example, our CY 2013, 2015, and 2017 PFS final rules, where we finalized new coding to provide separate payment for transitional care management services, chronic care management services, and behavioral health care management services to improve payment accuracy to better recognize resources involved in care management and coordination for certain patient populations (77 FR 68978, 79 FR 67715 and 82 FR 53163, respectively). To improve payment accuracy, we are exploring ways to better identify and value practitioners' work when they incur additional time and resources helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with the practitioner's ability to execute a medically necessary plan of care. Practitioners and their staff of auxiliary personnel sometimes obtain information about and help address, social determinants of health (SDOH) that significantly impact the practitioner's ability to diagnose or treat a patient. Additionally, practitioners and their staff of auxiliary personnel sometimes help newly diagnosed cancer patients and other patients with similarly serious, high-risk illnesses navigate their care, such as helping them understand and implement the plan of care, and locate and reach the right practitioners and providers to access recommended treatments and diagnostic services, taking into account the personal circumstances of each patient. Payment for these activities, to the extent they are reasonable and necessary for the diagnosis and treatment of the patient's illness or injury, is currently included in payment for other services such as evaluation and management (E/M) visits and some care management services. Medical practice has evolved to increasingly recognize the importance of these activities, and we believe practitioners are performing them more often. However, this work is not explicitly identified in current coding, and as such, we believe it is

underutilized and undervalued. Accordingly, we are proposing to create new coding to expressly identify and value these services for PFS payment, and distinguish them from current care management services. We expect that our proposed new codes would also support the CMS pillars [4] for equity, inclusion, and access to care for the Medicare population and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care. They would also support the White House's National Strategy on Hunger, Nutrition and Health, and the White House's Cancer Moonshot Initiative.[5]

As part of this effort, in the CY 2023 PFS final rule (87 FR 69551 through 69551), we issued a Request for Information (RFI) related to Medicare Part B Payment for services involving Community Health Workers (CHWs). For CY 2024, we are considering how we could better recognize, through coding and payment policies, when members of an interdisciplinary team, including CHWs, are involved in treatment of Medicare beneficiaries. Currently, there is no separately enumerated statutory Medicare benefit category that provides direct payment to CHWs for their services. Additionally, current HCPCS coding does not specifically identify services provided by CHWs, even though CHWs may facilitate access to healthcare through community-based services that are necessary to alleviate barriers to care that are interfering with a practitioner's ability to diagnosis or treat an illness or injury. In rulemaking for the CY 2023 PFS, to gain a broader perspective on CHWs and how we could refine our coding and payment policies to better recognize their role in furnishing Medicare-covered services, we solicited comment through an RFI on how services involving CHWs are furnished in association with the specific Medicare benefits established by the statute.

Commenters were supportive overall of potential, separate coding and payment for services involving CHWs. The public comments indicated that a number of physicians, practitioners, group practices, and other entities currently utilize the services of CHWs to bridge gaps in the continuum of their medical and behavioral healthcare furnished to Medicare patients. In public comments on our RFI, interested parties provided testimonials and evidence about the effectiveness of CHWs and the services that they provide to patients in the community by monitoring, interpreting, clarifying, and supporting the plans of care that physicians and practitioners establish for delivering care to patients.

In addition, in 2021, the AMA CPT Editorial Panel recognized in the CPT E/M Guidelines that SDOH needs can increase complexity of a practitioner's medical decision making (MDM) for an E/M visit and increase risk to the patient, when diagnosis or treatment is significantly limited by SDOH.[6] Specifically, the CPT Editorial Panel included as an example of moderate level MDM for E/M visit coding and level selection, a situation where diagnosis or treatment is significantly limited by SDOH. This situation is listed as an example of moderate risk of morbidity from additional diagnostic testing or treatment. The CPT E/M Guidelines defined SDOH as, ''Economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity.'' [7] We adopted these revised CPT guidelines for MDM in E/M visits through notice and comment rulemaking, effective January 1, 2021 (84 FR 62844 through 62860, 87 FR 69587 through 69614).

Physicians and NPPs are generally trained to obtain a patient's social and family history, in support of patient-centered care, to aid in diagnosis, and to better understand and help address problem(s) addressed in a medical visit and associated risk factors.[8] For example, a practitioner who discovers that a patient's living situation does not permit reliable access to electricity may need to prescribe an inhaler rather than a power-operated nebulizer to treat asthma. Some practices and facilities employ social workers or other ancillary staff to help address SDOH needs that are impacting the ability to provide medically necessary care, such as appropriate treatment or diagnostic services after an office visit or following discharge from a facility.

Practitioners are increasingly expending resources to obtain information from the patient about health-related social needs and risks, and formulate diagnosis and treatment plans that take these needs into account. We believe that social workers, CHWs and other auxiliary personnel are currently performing some of these activities, and that the resources involved in these activities are not consistently appropriately reflected in current coding and payment policies. As such, we believe it would be appropriate to create codes to separately identify and more accurately value this work. Accordingly, we are proposing new coding to describe and separately value three types of services that may be provided by auxiliary personnel incident to the billing physician or practitioner's professional services, and under the billing practitioner's supervision, when reasonable and necessary to diagnose and treat the patient: community health integration services, SDOH risk assessment, and principal illness navigation. This section of our proposed rule lays out the proposed codes and their proposed valuation, and describes the circumstances under which we believe these services may be reasonable and necessary for the diagnosis or treatment of illness or injury such that Medicare payment may be made for them.

b. Community Heath Integration (CHI) Services

In light of the feedback we have received from our RFI regarding CHWs, and increased recognition within the medical community of the role that social needs can play in patients' health (specifically, interfering with ability to diagnose and treat patients), we are proposing to establish separate coding and payment for community health integration (CHI) services. We are proposing to create two new G codes describing CHI services performed by certified or trained auxiliary personnel, which may include a CHW, incident to the professional services and under the general supervision of the billing practitioner. We are proposing that CHI services could be furnished monthly, as medically necessary, following an initiating E/M visit (CHI initiating visit) in which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the visit.

[4] CMS Strategic Plan | CMS.

[5] White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf (*whitehouse.gov*); Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It | The White House *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/.*

[6] 2021 CPT Codebook, p. 16.

[7] 2021 CPT Codebook, p. 14.

[8] See for example Patient-Centered Communication: Basic Skills | AAFP; *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html*; *https://doi.org/10.7326/M17-2441; https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/*; *https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf*; *https://edhub.ama-assn.org/steps-forward/module/2702762.* The Origins of the History and Physical Examination—Clinical Methods—NCBI Bookshelf (*nih.gov*) *https://www.ncbi.nlm.nih.gov/books/NBK458/.*

We propose that the CHI initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will also be furnishing the CHI services during the subsequent calendar month(s). The CHI initiating visit would be separately billed (if all requirements to do so are met), and would be a pre-requisite to billing for CHI services. We believe that certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as CHI initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary CHI services in the subsequent month(s).

The CHI initiating visit would serve as a pre-requisite to billing for CHI services, during which the billing practitioner would assess and identify SDOH needs that significantly limit the practitioner's ability to diagnose or treat the patient's medical condition and establish an appropriate treatment plan. The subsequent CHI services would be performed by a CHW or other auxiliary personnel incident to the professional services of the practitioner who bills the CHI initiating visit. The same practitioner would furnish and bill for both the CHI initiating visit and the CHI services, and CHI services must be furnished in accordance with the ''incident to'' regulation at § 410.26. We would not require an initiating E/M visit every month that CHI services are billed, but only prior to commencing CHI services, to establish the treatment plan, specify how addressing the unmet SDOH need(s) would help accomplish that plan, and establish the CHI services as incident to the billing practitioner's service. This framework is similar to our current requirements for billing care management services, such as chronic care management services. It also comports with our longstanding policy in the Medicare Benefit Policy Manual which provides, ''where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part. This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment'' (Chapter 15, Section 60.1.B of the Medicare Benefit Policy Manual (Pub. 100–02), available on our website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf* (*cms.gov*)).

We are also seeking comment on whether we should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite initiating visit for CHI services, including, for example, an annual wellness visit (AWV) that may or may not include the optional SDOH risk assessment also proposed in this rule. Under section 1861(hhh)(3)(C) of the Act, the AWV can be furnished by a physician or practitioner, or by other types of health professionals whose scope of practice does not include the diagnosis and treatment involved in E/M services, for example a health educator. When the AWV is furnished by other types of health professionals, it is not necessarily furnished incident to the professional services of a physician or other practitioner. Therefore, if we were to allow an AWV furnished by a health care practitioner other than a physician or practitioner to serve as the initiating visit for CHI services, the CHI services would not necessarily be furnished consistent with our proposed application of the ''incident to'' regulations as a condition of payment. Further, we believe that practitioners would normally bill an E/M visit in addition to the AWV when medical problems are addressed in the course of an AWV encounter, in accordance with our manual policy providing that a medically necessary E/M visit may be billed when furnished on the same occasion as an AWV in those circumstances (Chapter 12, Section 30.6.1.1.H of the Medicare Claims Processing Manual (Pub. 100–04).

For purposes of assigning a supervision level for these ''incident to'' services, we are proposing to designate CHI services as care management services that may be furnished under the general supervision of the billing practitioner in accordance with § 410.26(b)(5). General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service (§ 410.26(a)(3)).

In this proposal, the phrase or term ''problem addressed'' refers to the definition in the CPT E/M Guidelines that we have adopted for E/M visits. Specifically, ''[a] problem is a disease, condition, illness, injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter. Problem addressed [means the following]: A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified healthcare professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice. Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. Referral without evaluation (by history, examination, or diagnostic study[ies]) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. For hospital inpatient and observation care services, the problem addressed is the problem status on the date of the encounter, which may be significantly different than on admission. It is the problem being managed or co-managed by the reporting physician or other qualified healthcare professional and may not be the cause of admission or continued stay'' (2023 CPT Codebook, p. 6–8).

For purposes of CHI services (and PIN services discussed later in this section), we propose that SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in these same CPT E/M Guidelines (2023 CPT codebook, page 11). We are proposing to adopt CPT's examples of SDOH, with additional examples. Specifically, we are proposing that SDOH(s) may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the CHI initiating visit. Since Medicare payment generally is limited to items and services that are reasonable and necessary for the

diagnosis or treatment of illness or injury, the focus of CHI services would need to be on addressing the particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit.

We propose the following specific codes and descriptors:

GXXX1 *Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:*

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.*

++ Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

- *Practitioner, Home-, and Community-Based Care Coordination.*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (*e.g.,* housing, utilities, transportation, food assistance) to address the SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access/health system navigation*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

By way of example, tailored support could be provided through CHI services to a patient experiencing homelessness with signs of potential cognitive impairment and a history of frequent ED admissions for uncontrolled diabetes. The patient's primary care practitioner (PCP) learns during a clinic visit after discharge from the ED, that the patient has been able to reliably fill their prescriptions for diabetes medication, but frequently loses the medication (or access to it) while transitioning between homeless shelters and a local friend's home. In the medical record, the PCP documents SDOH need(s) of housing insecurity and transportation insecurity contributing to medication noncompliance, resulting in inadequate insulin control and a recent ED visit for hypoglycemia. The PCP's treatment plan is daily diabetes medication, with the goal of maintaining hemoglobin A1c within appropriate levels. To accomplish the treatment plan, the PCP orders CHI services to develop an individualized plan for daily medication adherence/access while applying for local housing assistance, and also orders a follow up visit for cognitive impairment assessment and care planning to further evaluate the potential contribution of cognitive impairment. The PCP's auxiliary personnel provide tailored support, comprised of facilitating communication between the patient, local shelters, and the friend, to help the patient identify a single location to reliably store their medication while applying for local housing assistance. The auxiliary personnel also help the patient identify a reliable means of transportation daily to that location for their medication, and show the patient how to create a daily automated phone reminder to take the diabetes medication. The auxiliary personnel document these activities (including amount of time spent) in the medical record at the PCP's office, along with periodic updates regarding the status of the patient's housing assistance application.

To help inform whether our proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, we are seeking comment on the typical amount of time practitioners spend per month furnishing CHI services to address SDOH needs that pose barriers to diagnosis and treatment of problem(s) addressed in an E/M visit. We are also seeking comment to better understand the typical duration of CHI services, in terms of the number of months for which practitioners furnish the services.

We are proposing that all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements, and authorized to perform them under applicable State laws and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide the services performed incident to the billing practitioner's professional services, including licensure, that are imposed by the State in which the services are being furnished. In States where there are no applicable licensure or other laws or regulations relating to individuals performing CHI services, we are proposing to require auxiliary personnel providing CHI services to be trained to provide them. Training must include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity-building, service coordination and system navigation,

patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including of local community-based resources. We are proposing these competencies because they reflect professional consensus regarding appropriate core competencies for CHWs, applied to this context.[9] We are seeking public comment on whether it would be appropriate to specify the number of hours of required training, as well as the training content and who should provide the training.

We are proposing to require that time spent furnishing CHI services for purposes of billing HCPCS codes GXXX1–2 must be documented in the patient's medical record in its relationship to the SDOH need(s) they are intended to address and the clinical problem(s) they are intended to help resolve. The activities performed by the auxiliary personnel would be described in the medical record, just as all clinical care is documented in the medical record. We are proposing to require the SDOH need(s) to be recorded in the patient's medical record, and for data standardization, practitioners would be encouraged to record the associated ICD–10 Z–code (Z55–Z65) in the medical record and on the claim.

Since CHI services are community-based and involve connecting the patient with local resources in their community, and are highly personalized, *e.g.,* hearing and understanding a patient's life story and culture, we believe that most of the elements of CHI services would involve direct contact between the auxiliary personnel and the patient, and that a substantial portion would be in-person but a portion might be performed via two-way audio. We are seeking to confirm our understanding of where and how these services would be typically provided (*e.g.,* in-person, audio-video, two-way audio).

We are seeking public comment, in particular, regarding whether we should require patient consent for CHI services. For care management services that could generally be performed without any direct patient contact, we require advance patient consent to receive the services as a prerequisite to furnishing and billing the services, to avoid patients receiving bills for cost sharing that they might not be expecting to receive. For example, a patient might receive chronic care management services comprised of practitioners coordinating care with each other and reviewing or exchanging medical records between visits in ways that do not require involving the patient directly. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have statutory authority to waive cost sharing for care management or other services. Rather, cost sharing remains applicable except as specified by statute such as for certain preventive services. In recent years, we have required advance documented patient consent to receive most care management services as a condition of the practitioner billing those services, to avoid a situation where the patient is surprised to receive a bill for the associated cost sharing. These consent requirements include informing the patient about applicable cost sharing, the right to discontinue services, and, where applicable, the limitation that payment is made for the service to only one practitioner per month. We have heard from interested parties over time that requiring advance patient consent is an administrative burden and may pose a barrier to receipt of needed services. We are not proposing to require consent for CHI services, since we believe these services typically would involve direct patient contact, and largely be provided in-person. However, if we hear from public commenters that CHI services would frequently not involve direct contact with the patient, or could extend for periods of time for which the patient might not be expecting to incur cost sharing obligations (such as multiple months), we would consider requiring patient consent to receive CHI services in our final rule.

We are proposing that a billing practitioner may arrange to have CHI services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of CHI services are met. While we are proposing to allow CHI services to be performed by auxiliary personnel under a contract with a third party, we wish to be clear, as we have in our regulations for current care management services, that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained. As we discussed in a similar context for care management services the CY 2017 PFS final rule, if there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing the services and the billing practitioner, we do not believe CHI services, as we propose to define them, could be fully performed; and therefore, in such cases, CHI services should not be billed (see 81 FR 80249). We would expect the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner to ensure that CHI services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for CHI services to address the SDOH need(s) that limit the practitioner's ability to diagnose and treat the problem(s) addressed in the initiating visit.

As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. As described earlier, they may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve, and may have the infrastructure or systems in place to assist practitioners to provide CHI services. We understand that many CBOs provide social services and do other work that is beyond the scope of CHI services, but we believe they are well-positioned to develop relationships with practitioners for providing reasonable and necessary CHI services.

Because we are concerned about potential fragmentation that could occur in addressing specific SDOH, we are proposing that only one practitioner per beneficiary per calendar month could bill for CHI services. This would allow

[9] *https://chwtraining.org/c3-project-chw-skills/.*

the patient to have a single point of contact for all their CHI services during a given month.

We are proposing that the practitioner could separately bill for other care management services during the same month as CHI services, if time and effort are not counted more than once, requirements to bill the other care management service are met, and the services are medically reasonable and necessary.

We propose that CHI services could not be billed while the patient is under a home health plan of care under Medicare Part B, since we believe there would be significant overlap between services furnished under a home health plan of care and CHI services, particularly in the home health services referred to as ''medical social services,'' and in comprehensive care coordination. For example, medical social services can be furnished to the patient's family member or caregiver on a short-term basis when the home health agency (HHAs) can demonstrate that a brief intervention by a medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the patient's medical condition or to the patient's rate of recovery. Additionally, the home health agency (HHA) conditions of participation require that HHAs coordinate all aspects of the beneficiary's care while under a home health plan of care, such as integrating services, whether provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines; and involvement of the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

Also, we note that when Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. Based on the specificity of the coding for our proposal, we do not expect that CHI services will neatly overlap with any other coverage for patients who are dually eligible for Medicare and Medicaid. However, we are seeking public comment regarding whether States typically cover services similar to CHI under their Medicaid programs, and whether such coverage would be duplicative of the CHI service codes. We also seek comment on whether there are other service elements not included in the proposed CHI service codes that should be included, or are important in addressing unmet SDOH need(s) that affect the diagnosis or treatment of medical problems, where CMS should consider coding and payment in the future.

c. Proposed CHI Services Valuation

For HCPCS code GXXX1, we are proposing a work RVU of 1.00 based on a crosswalk to CPT code 99490 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) as we believe these values most accurately reflect the resource costs incurred when the billing practitioner furnishes CHI services. CPT code 99490 has an intraservice time of 25 minutes and the work is of similar intensity to our proposed HCPCS code GXXX1. We are, therefore, proposing a work time of 25 minutes for HCPCS code GXXX1, based on this same crosswalk to CPT code 99490. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GXXX1.

For HCPCS code GXXX2, we are proposing a crosswalk to the work RVU and direct PE inputs associated with CPT code 99439 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*) as we believe these values reflect the resource costs incurred when the billing practitioner furnishes CHI services. Therefore, we are proposing a work RVU of 0.70 and a work time of 20 minutes for HCPCS code GXXX2.

d. Social Determinants of Health (SDOH)—Proposal To Establish a Stand-Alone G Code

i. Background

As previously discussed, there is increasing recognition within the health care system of the need to take SDOH into account when providing health care services, given that it is estimated [10] that around 50 percent of an individual's health is directly related to SDOH. Healthy People 2030 define the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context, which include factors like housing, food and nutrition access, and transportation needs. Many Federal agencies are also developing policies to better address the impact SDOH have on patients, in support of HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity,[11] as well as the CMS Framework for Health Equity.[12]

ii. Proposed SDOH Risk Assessment Code

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients, including by recommending the assessment of SDOH through position or discussion papers,[13] [14] [15] organizational strategic plans,[16] and provider training modules.[17] Previously in this section of our proposed rule, we discuss how the practice of medicine currently includes assessment of health-related social needs or SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally

[10] *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*

[11] *https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf.*

[12] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[13] *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html.*

[14] *https://doi.org/10.7326/M17-2441.*

[15] *https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/.*

[16] *https://www.ama-assn.org/system/files/2021-05/ama-equity-strategic-plan.pdf.*

[17] *https://edhub.ama-assn.org/steps-forward/module/2702762.*

performed by physicians and practitioners in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. We believe the resources involved in these activities are not appropriately reflected in current coding and payment policies. As such, we are proposing to establish a code to separately identify and value a SDOH risk assessment that is furnished in conjunction with an E/M visit.

We are proposing a new stand-alone G code, GXXX5, *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months.* SDOH risk assessment refers to a review of the individual's SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions. We are proposing GXXX5 to identify and value the work involved in the administering a SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. SDOH risk assessment through a standardized, evidence-based tool can more effectively and consistently identify unmet SDOH needs, and enable comparisons across populations. For example, through administration of the SDOH risk assessment for a patient presenting for diabetes management, a practitioner might discover that a patient's living situation does not permit reliable access to electricity, impacting the patient's ability to keep insulin refrigerated. The practitioner may then prescribe a type of insulin that remains stable at room temperature, or consider oral medication instead. In this example, the practitioner could furnish an SDOH risk assessment in conjunction with the E/M visit to gain a more thorough understanding of the patient's full social history and to determine whether other SDOH needs are also impacting medically necessary care.

We further propose that the SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. Required elements would include:

- Administration of a standardized, evidence-based [18] SDOH risk assessment tool that has been tested and validated through research, and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.

++ Billing practitioners may choose to assess for additional domains beyond those listed above if there are other prevalent or culturally salient social determinants in the community being treated by the practitioner.

Possible evidence-based tools include the CMS Accountable Health Communities [19] tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) [20] tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.[21]

Given the multifaceted nature of unmet SDOH needs, appropriate follow-up is critical for mitigating the effects of the identified, unmet SDOH needs on a person's health. An SDOH risk assessment without appropriate follow-up for identified needs would serve little purpose. As such, CMS is seeking comment on whether we should require as a condition of payment for SDOH risk assessment that the billing practitioner also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with community-based organizations (CBO) to address identified SDOH needs.

The SDOH needs identified through the risk assessment must be documented in the medical record, and may be documented using a set of ICD–10–CM codes known as ''Z codes'' [22] (Z55–Z65) which are used to document SDOH data to facilitate high-quality communication between providers. We are proposing GXXX5 have a duration of 5–15 minutes for the administration of an SDOH risk assessment tool, billed no more often than once every 6 months. We propose to limit the SDOH assessment service to once every six months, as we believe there are generally not significant, measurable changes to health outcomes impacted by a patient's SDOH in intervals shorter than 6 months.

iii. Proposed Valuation for SDOH Risk Assessment GXXX5

We propose a direct crosswalk to HCPCS code G0444 (*Screening for depression in adults, 5–15 minutes*), with a work RVU of 0.18, as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code GXXX5. HCPCS code G0444 has an intraservice time of 15 minutes, and the physician work is of similar intensity to our proposed HCPCS code GXXX5. Therefore, we are proposing a work time of 15 minutes for HCPCS code GXXX5 based on this same crosswalk to G0444. We are also proposing to use this crosswalk to establish the direct PE inputs for HCPCS code GXXX5.

We believe these services would largely involve direct patient contact between the billing practitioner or billing practitioner's auxiliary personnel and the patient through in-person interactions, which could be conducted via telecommunications as appropriate. Therefore, we are proposing to add this code to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner (or their auxiliary personnel incident to the practitioner's services) completes the risk assessment in an interview format, if appropriate. We believe it is important that when furnishing this service, all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We are seeking comment on where and how these services would be typically provided, along with other aspects of the proposed SDOH assessment service.

e. Principal Illness Navigation (PIN) Services

i. Background

Experts on navigation of treatment for cancer and other high-risk, serious illnesses have demonstrated the benefits of navigation services for patients experiencing these conditions.[23] Experts have noted the importance of these services for all affected patients, but especially those with socioeconomic disadvantages or barriers to care. Navigation generally means the process or activity of ascertaining one's position and planning and following a route; the act of directing from one place to another; the skill or process of plotting a route and directing; the act, activity, or process of finding the way to get to a place you are traveling. In the context of healthcare, it refers to providing individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely, especially when the landscape is complex and delaying care can be deadly. It is often referred

[18] *https://health.gov/healthypeople/tools-action/browse-evidence-based-resources/types-evidence-based-resources.*

[19] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[20] *https://www.nachc.org/research-and-data/prapare/.*

[21] CMS–10825.

[22] *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[23] See for example, *https://view.ons.org/3hjHjc* and *https://www.accc-cancer.org/docs/projects/pdf/patient-navigation-guide.*

to in the context of patients diagnosed with cancer or another severe, debilitating illness, and includes identifying or referring to appropriate supportive services. It is perhaps most critical when a patient is first undergoing treatment for such conditions, due to the extensive need to access and coordinate care from a number of different specialties or service-providers for different aspects of the diagnosis or treatment, and in some cases, related social services (for example, surgery, radiation, chemotherapy for cancer; psychiatry, psychology, vocational rehabilitation for severe mental illness; psychiatry, psychology, vocational rehabilitation, rehabilitation and recovery programs for substance use disorder; infectious disease, neurology and immunology for human immunodeficiency virus (HIV)-associated neurocognitive disorders). For some conditions, patients are best able to engage with the healthcare system and access care if they have assistance from a single, dedicated individual who has ''lived experience'' (meaning they have personally experienced the same illness or condition the patient is facing). While we currently make separate payment under the PFS for a number of care management and other services that may include aspects of navigation services, those care management services are focused heavily on clinical aspects of care rather than social aspects, and are generally performed by auxiliary personnel who may not have lived experience or training in the specific illness being addressed. We are seeking to better understand whether there are gaps in coding for patient navigation services for treatment of serious illness, that are not already included in current care management services such as advance care planning services (CPT codes 99497–99498), chronic care management services (CPT codes 99490, 99439, 99491, 99437, 99487 and 99489), general behavioral health integration care management services (CPT code 99484), home health and hospice supervision (HCPCS codes G0181–G0182), monthly ESRD-related services (CPT codes 90951–90970), principal care management services (CPT codes 99424–99427), psychiatric collaborative care management services (CPT codes 99492–99494), and transitional care management services (CPT codes 99495–99496). See additional information on our PFS Care Management Services web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

For CY 2024, we are proposing to better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death. Examples of serious, high-risk diseases for which patient navigation services could be reasonable and necessary could include cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder. We are proposing new coding for Principal Illness Navigation (PIN) services. In considering the appropriate patient population, we considered the patient population eligible for principal care management service codes (CPT codes 99424 through 99427), as well as clinical definitions of ''serious illness.'' For example, one peer-review study defined ''serious illness'' as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers.[24] Another study describes a serious illness as a health condition that carries a high risk of mortality and commonly affects a patient for several years.[25] Some measure serious illness by the amount of urgent health care use (911 calls, emergency department visits, repeated hospitalizations) and polypharmacy.[26] The navigation services such patients need are similar to CHI services (as discussed previously in this section), but SDOH need(s) may be fewer or not present; and there are specific service elements that are more relevant for the subset of patients with serious illness. Accordingly, we are proposing for PIN services a parallel set of services to the proposed CHI services, but focused on patients with a serious, high-risk illness who may not necessarily have SDOH needs; and adding service elements to describe identifying or referring the patient to appropriate supportive services, providing information/resources to consider participation in clinical research/clinical trials, and inclusion of lived experience or training in the specific condition being addressed.

[24] *https://pubmed.ncbi.nlm.nih.gov/29125784/.*

[25] *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

[26] *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

ii. Proposed Principal Illness Navigation (PIN) Service Definition

PIN services could be furnished following an initiating E/M visit addressing a serious high-risk condition/illness/disease, with the following characteristics:

- One serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death;
- The condition requires development, monitoring, or revision of a disease-specific care plan, and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver.

Examples of a serious, high-risk condition/illness/disease include, but are not limited to, cancer, chronic obstructive pulmonary disease, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder.

We propose that the PIN initiating visit would be an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will also be furnishing the PIN services during the subsequent calendar month(s). The PIN initiating visit would be separately billed (if all requirements to do so are met), and would be a pre-requisite to billing for PIN services. We believe that certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as PIN initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient, including furnishing necessary PIN services in the subsequent month(s).

The PIN initiating visit would serve as a pre-requisite to billing for PIN services, during which the billing practitioner would identify the medical necessity of PIN services and establish an appropriate treatment plan. The subsequent PIN services would be performed by auxiliary personnel incident to the professional services of the practitioner who bills the PIN initiating visit. The same practitioner would furnish and bill for both the PIN initiating visit and the PIN services, and PIN services must be furnished in accordance with the ''incident to'' regulation at § 410.26. We would not require an initiating E/M visit every month that PIN services are billed, but

only prior to commencing PIN services, to establish the treatment plan, specify how PIN services would help accomplish that plan, and establish the PIN services as incident to the billing practitioner's service. This framework is similar to our current requirements for billing care management services, such as chronic care management services. It also comports with our longstanding policy in the Medicare Benefit Policy Manual which provides, ''where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part. This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment'' (Chapter 15, Section 60.1.B of the Medicare Benefit Policy Manual (Pub. 100–02), available on our website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf*.

We are also seeking comment on whether we should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite initiating visit for PIN services, including, for example, an annual wellness visit (AWV) that may or may not include the optional SDOH risk assessment also proposed in this rule. Under section 1861(hhh)(3)(C) of the Act, the AWV can be furnished by a physician or practitioner, or by other types of health professionals whose scope of practice does not include the diagnosis and treatment involved in E/M services, for example a health educator.

When the AWV is furnished by other types of health professionals, it is not necessarily furnished incident to the professional services of a physician or other practitioner. Therefore, if we were to allow an AWV furnished by a health care practitioner other than a physician or practitioner to serve as the initiating visit for PIN services, the PIN services would not necessarily be furnished consistent with our proposed application of the ''incident to'' regulations as a condition of payment. Further, we believe that practitioners would normally bill an E/M visit in addition to the AWV when medical problems are addressed in the course of an AWV encounter, in accordance with our manual policy providing that a medically necessary E/M visit may be billed when furnished on the same occasion as an AWV in those circumstances (Chapter 12, Section 30.6.1.1.H of the Medicare Claims Processing Manual (Pub, 100–04).

For purposes of assigning a supervision level for payment, we are proposing to designate PIN services as care management services that may be furnished under general supervision under § 410.26(b)(5). General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service (§ 410.26(a)(3)).

We propose the following codes for PIN services. As described previously, and in our proposed PIN code descriptors, the term ''SDOH need(s)'' means an SDOH need(s) that is identified by the billing practitioner as significantly limiting the practitioner's ability to diagnose or treat the serious, high-risk condition/illness/disease addressed in the initiating E/M visit. ''Addressed'' means the definition in the CPT E/M Guidelines that we have adopted for E/M visits. Specifically, ''[a] problem is a disease, condition, illness, injury, symptom, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter. Problem addressed [means the following]: A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified healthcare professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice. Notation in patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. Referral without evaluation (by history, examination, or diagnostic study[ies]) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified healthcare professional reporting the service. For hospital inpatient and observation care services, the problem addressed is the problem status on the date of the encounter, which may be significantly different than on admission. It is the problem being managed or co-managed by the reporting physician or other qualified healthcare professional and may not be the cause of admission or continued stay'' (2023 CPT Codebook, pages. 6 through 8).

For purposes of PIN services, we propose that SDOH means economic and social condition(s) that influence the health of people and communities, as indicated in these same CPT E/M Guidelines (2023 CPT codebook, page 11). We are proposing to adopt CPT's examples of SDOH, with additional examples. Specifically, we are proposing that SDOH(s) may include but are not limited to food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities, when they significantly limit the practitioner's ability to diagnose or treat the serious, high-risk illness/condition/disease. Since Medicare payment is limited to items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, with respect to addressing SDOH need(s), the focus of PIN services would need to be on addressing particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the serious, high-risk condition.

GXXX3 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal setting and establishing an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Coordination*

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and*

community-based service providers; and caregiver (if applicable).

++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.

++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

To help inform whether our proposed descriptor times are appropriate and reflect typical service times, and whether a frequency limit is relevant for the add-on code, we are seeking comment on the typical amount of time practitioners spend per month furnishing PIN services. We are also seeking comment to better understand the typical duration of PIN services, in terms of the number of months for which practitioners furnish PIN services following an initiating visit.

We are proposing that all auxiliary personnel who provide PIN services must be certified or trained to provide all included PIN service elements, and be authorized to perform them under applicable State law and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. Many States have applicable rules and certifications, and there are existing certification programs for navigators working in certain settings of care or with specified conditions, such as cancer navigators, diabetes navigators, cardiovascular navigators, mental health navigators, geriatric care navigators, pediatric navigators, social worker navigators, primary care navigators, general patient advocate navigators, and nurse navigators in ambulatory settings.[27] Approximately 48 States have professional certification programs for peer support specialists providing services to patients with substance use or mental health conditions, which is required for billing peer support specialists' services to Medicaid. For substance use and mental health conditions, SAMHSA recently published National Model Standards for Peer Support Certification.[28]

In States that do not have applicable licensure, certification, or other laws or regulations, we are proposing to require auxiliary personnel providing PIN services to be trained to provide them. Training must include the competencies of patient and family communication, interpersonal and relationship-building, patient and family capacity building, service coordination and systems navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including specific certification or training on the serious, high-risk condition/illness/disease addressed in the initiating visit. We are proposing these competencies because we believe they reflect professional consensus regarding appropriate core competencies, adjusted to this context.[29] We are seeking public comment on the number of hours of training to require, as well as the training content and who should provide the training.

We are proposing that time spent furnishing PIN services for purposes of billing HCPCS codes GXXX3–4 must be documented in the medical record in its relationship to the serious, high-risk illness. The activities performed by the auxiliary personnel, and how they are related to the treatment plan for the serious, high-risk condition, would be described in the medical record, just as all clinical care is documented in the medical record. We would require identified SDOH need(s), if present, to be recorded in the medical record, and for data standardization, practitioners would be encouraged to record the associated ICD–10 Z-code (Z55–Z65) in the medical record and on the claim.

Similar to CHI services (discussed previously in this proposed rule), we believe that many of the elements of PIN services would involve direct contact between the auxiliary personnel and the patient, but may not necessarily be in-person and a portion might be performed via two-way audio. We are seeking to confirm our understanding of where and how PIN services would be typically provided (for example, with or without direct patient contact, in-person, using audio-video, using two-way audio; and whether navigators are typically local to the patient).

We are seeking public comment in particular regarding whether we should require patient consent for PIN services. For care management services that could generally be performed without any direct patient contact, we require advance patient consent to receive the services as a prerequisite to furnishing and billing the services, to avoid patients receiving bills for cost sharing

[27] *https://resumecat.com/blog/patient-navigator-certifications.*

[28] *https://peerrecoverynow.org/product/comparative-analysis-of-state-requirements-for-peer-support-specialist-training-and-certification-in-the-us/* and *https://store.samhsa.gov/sites/default/files/pep23-10-01-001.pdf.*

[29] *https://view.ons.org/3hjHjc* and *https://www.accc-cancer.org/docs/projects/pdf/patient-navigation-guide*; *https://chwtraining.org/c3-project-chw-skills/*; and *https://peerrecoverynow.org/wp-content/uploads/Comparative-Analysis_Jan.31.2022-003.pdf*; *https://www.samhsa.gov/sites/default/files/national-model-standards-for-peer-support-certification.pdf?utm_source=SAMHSA&utm_campaign=4b88ba3e51-EMAIL_CAMPAIGN_2023_06_05_02_41&utm_medium=email&utm_term=0_-4b88ba3e51-%5BLIST_EMAIL_ID%5D.*

that they might not be expecting to receive. For example, a patient might receive chronic care management services comprised of practitioners coordinating care with each other and reviewing or exchanging medical records between visits, in ways that do not require involving the patient directly. As we have frequently discussed in prior rulemaking for care management services (for example, at 81 FR 80240), we do not have statutory authority to waive cost sharing for care management or other services. Rather, cost sharing remains applicable, except as specified by statute such as for certain preventive services. In recent years, we have required advance documented patient consent to receive most care management services as a condition of the practitioner billing those services, to avoid a situation where the patient is surprised to receive a bill for the associated cost sharing. These consent requirements include informing the patient about applicable cost sharing, the right to discontinue services, and, where applicable, the limitation that payment is made for the service to only one practitioner per month. We have heard from interested parties over time that requiring advance patient consent is an administrative burden and may unnecessarily prevent patient receipt of needed services. We are not proposing to require consent for PIN services, since we believe these services typically would involve direct patient contact, and largely be provided in-person. However, if we hear from public commenters that PIN services would frequently not involve direct contact with the patient, or could extend for periods of time for which the patient might not be expecting to incur cost sharing obligations (such as several months), we would consider requiring patient consent to receive PIN services in our final rule.

We are proposing that a billing practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of PIN services are met. While we are proposing to allow PIN services to be performed by auxiliary personnel under a contract with a third party, we wish to be clear, as we have in our regulations for current care management services, that there must be sufficient clinical integration between the third party and the billing practitioner in order for the services to be fully provided, and the connection between the patient, auxiliary personnel, and the billing practitioner must be maintained. As we discussed in a similar context for care management services the CY 2017 PFS final rule, if there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing the services and the billing practitioner, we do not believe PIN services, as we propose to define them, could be fully performed; and therefore, in such cases, PIN services should not be billed (81 FR 80249). We would expect the auxiliary personnel performing the PIN services to communicate regularly with the billing practitioner to ensure that PIN services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for PIN services to address the serious, high-risk condition.

In the CY 2023 final rule (87 FR 69790) and as explained in the CY 2023 PFS proposed rule (87 FR 46102), where we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. As described earlier, they may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve, and may have the infrastructure or systems in place to assist practitioners to provide PIN services. We understand that many CBOs provide social services and do other work that is beyond the scope of PIN services, but we believe they are well-positioned to develop relationships with practitioners for providing reasonable and necessary PIN services.

We are proposing that only one practitioner per beneficiary per calendar month could bill for PIN services for a given serious, high-risk condition, because we are concerned about potential care fragmentation if the patient has more than one navigator for their condition during a given month. Our proposal would allow the patient to have a single point of contact for navigation of their condition.

We are proposing that the practitioner could bill separately for other care management services during the same month as PIN, if time and effort are not counted more than once, requirements to bill the other care management services are met, and the services are medically reasonable and necessary.

Similar to CHI service (as discussed previously in this proposed rule), there are aspects of PIN services, or PIN services for certain conditions, that may be covered under a Medicaid program. When Medicare and Medicaid cover the same services for patients eligible for both programs, Medicare generally is the primary payer in accordance with section 1902(a)(25) of the Act. We are seeking public comment regarding whether States typically cover services similar to PIN under their Medicaid programs, and whether such coverage would be duplicative of the PIN service codes. We also seek comment on if there are other service elements not included in the PIN service codes that are part of associated care that should be included in the PIN service codes, or are important in navigation for high-risk conditions, where CMS should consider coding and payment in the future. For example, are there circumstances when clinical navigators, under the supervision of another professional, typically spend time face-to-face with patients that the PIN services codes, as currently described, may not fully account for?

iii. Proposed PIN Services Valuation

For HCPCS code GXXX3, we are proposing a work RVU of 1.00 based on a crosswalk to CPT code 99490 (Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month) as we believe these values most accurately reflect the resource costs associated when the billing practitioner performs PIN services. CPT code 99490 has an

intraservice time of 25 minutes and the physician work is of similar intensity to our proposed HCPCS code GXXX3. Therefore, we are proposing a work time of 25 minutes for HCPCS code GXXX3 based on this same crosswalk to CPT code 99490. We are proposing to use this crosswalk as well to establish the direct PE inputs for HCPCS code GXXX3.

For HCPCS code GXXX4, we are proposing a crosswalk to the work RVU and direct PE inputs associated with CPT code 99439 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*) as we believe these values reflect the resource costs associated with the clinician's direction of clinical staff who are performing the PIN services. Therefore, we are proposing a work RVU of 0.70 and a work time of 20 minutes for HCPCS code GXXX4.

(28) Maternity Services (CPT codes 59400, 59410, 59425, 59426, 59430, 59510, 59515, 59610, 59614, 59618, 59622)

In the CY 2021 PFS final rule with comment period (85 FR 84554–84555), we finalized our proposal to revalue the bundled maternity codes used to bill for delivery, antepartum, and postpartum maternity care services to account for increases in the values of office/outpatient E/M services. These codes are all designated with a unique global period indicator ''MMM.'' There are 11 MMM codes that include E/M visits as part of their valuation.

For CY 2024, we are proposing to update the work RVUs and work times of these MMM codes to reflect any relevant E/M updates associated with their global periods that were finalized in CY 2023. Table 11 contains a list of these codes and the proposed work RVUs for CY 2024. MMM codes are unique within the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, which include a relatively large number of E/M visits performed along with delivery services and imaging; and were valued using a building-block methodology as opposed to the magnitude estimation method.

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TABLE 11: Current and Proposed Value for Each Maternity Services Code

CPT code	Current Work RVU value	2023 E/M adjustment value	New Work RVU Value
59400	36.58	0.42	**37.00**
59410	18.34	0.42	**18.76**
59425	7.80	0.00	**7.80**
59426	14.30	0.00	**14.30**
59430	3.22	0.00	**3.22**
59510	40.39	0.66	**41.05**
59515	22.13	0.66	**22.79**
59610	38.29	0.42	**38.71**
59614	20.06	0.42	**20.48**
59618	40.91	0.66	**41.57**
59622	22.66	0.66	**23.32**

TABLE 12: CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	27.13	27.13	27.13	No
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	C	7.50	6.88	No
2X000	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device	NEW	7.86	7.86	No
2X002	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	NEW	32.00	32.00	No
2X003	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	NEW	35.50	35.50	No
2X004	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	NEW	36.00	36.00	No
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach	3.26	3.91	3.91	No
30118	Excision or destruction (eg, laser), intranasal lesion; external approach (lateral rhinotomy)	9.92	9.55	7.75	No
3X008	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]) including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation when performed	NEW	9.50	9.50	No
3X009	Insertion of phrenic nerve stimulator transvenous sensing lead	NEW	5.43	5.43	No
3X010	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)	NEW	9.55	9.55	No
3X011	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only	NEW	5.42	5.42	No
3X012	Removal of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only	NEW	3.04	3.04	No
3X013	Repositioning of phrenic nerve stimulator transvenous lead(s)	NEW	6.00	6.00	No
3X014	Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; pulse generator	NEW	6.05	6.05	No
3X015	Removal and replacement of phrenic nerve stimulator including vessel catheterization, all imaging guidance, and interrogation and programming when performed; transvenous stimulation or sensing lead	NEW	8.51	8.51	No
3X016	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve	NEW	2.70	2.70	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
3X017	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve	NEW	2.70	2.70	No
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	36.58	-	37.00	Yes
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.34	-	18.76	Yes
59425	Antepartum care only; 4-6 visits	7.80	-	7.80	No
59426	Antepartum care only; 7 or more visits	14.30	-	14.30	No
59430	Postpartum care only (separate procedure)	3.22	-	3.22	No
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	40.39	-	41.05	Yes
59515	Cesarean delivery only; including postpartum care	22.13	-	22.79	Yes
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	38.29	-	38.71	Yes
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	20.06	-	20.48	Yes
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	40.91	-	41.57	Yes
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	22.66	-	23.32	Yes
5X000	Excision or destruction (eg, laser), intranasal lesion; internal approach	NEW	3.10	3.10	No
5X005	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency	NEW	7.21	7.21	No
619X1	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	NEW	25.75	25.75	No
619X2	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)	NEW	11.25	11.25	No
619X3	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed	NEW	15.00	15.00	No
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver requiring pocket creation and connection between electrode array and pulse generator or receiver	5.19	5.19	5.19	No
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array, with detachable connection to	5.30	4.35	4.35	No
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver direct or inductive coupling, requiring pocket creation and connection between electrode array and pulse generator or receiver	2.45	5.10	5.10	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array	1.78	3.79	3.79	No
64XX2	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; initial electrode array	NEW	C	C	No
64XX3	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator including imaging guidance, when performed; each additional electrode array	NEW	C	C	No
64XX4	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	NEW	C	C	No
65778	Placement of amniotic membrane on the ocular surface; without sutures	1.00	0.84	0.84	No
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured	2.50	1.75	1.75	No
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers	7.81	7.03	7.03	No
6X000	Suprachoroidal space injection of pharmacologic agent (separate procedure)	NEW	1.53	1.53	No
76881	Ultrasound, complete joint (ie, joint space and periarticular soft-tissue structures), real-time with image documentation	0.90	0.90	0.90	No
76882	Ultrasound, limited, joint or focal evaluation of other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft tissue mass[es]), real-time with image documentation	0.69	0.69	0.69	No
76883	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity	1.21	1.21	1.21	No
76937	Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting	0.30	0.30	0.30	No
76998	Ultrasonic guidance, intraoperative	1.20	1.20	0.91	No
7X000	Ultrasound, intraoperative thoracic aorta (eg, epiaortic), diagnostic	NEW	0.60	0.60	No
7X001	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	NEW	1.90	1.62	No
7X002	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only	NEW	1.20	1.08	No
7X003	Intraoperative epicardial cardiac (eg, echocardiography) ultrasound for congenital heart disease, diagnostic; interpretation and report only	NEW	1.55	0.54	Yes
7X005	Noninvasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the data set from a coronary computed tomography angiography,	NEW	0.75	0.75	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	with interpretation and report by a physician or other qualified health care professional				
90832	Psychotherapy, 30 minutes with patient	1.70	-	1.78	No
90834	Psychotherapy, 45 minutes with patient	2.24	-	2.35	No
90837	Psychotherapy, 60 minutes with patient	3.31	-	3.47	No
90839	Psychotherapy for crisis; first 60 minutes	3.13	-	3.28	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.50	-	1.57	No
90845	Psychoanalysis	2.10	-	2.20	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.40	-	2.51	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.50	-	2.62	No
90849	Multiple-family group psychotherapy	0.59	-	0.62	No
90853	Group psychotherapy (other than of a multiple-family group)	0.59	-	0.62	No
926X1	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes	NEW	1.25	1.25	No
926X2	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes	NEW	0.33	0.33	No
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
96202	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes	B	-	0.43	No
96203	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes	B	-	0.12	No
99484	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated	0.61	0.85	0.93	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team.				
99497	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate	1.50	1.50	1.50	No
99498	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes	1.40	1.40	1.40	No
9X000	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart	NEW	1.20	1.20	No
9X002	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemi-azygos venous system	NEW	1.13	1.13	No
9X003	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus	NEW	1.43	1.43	No
9X004	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (eg, from innominate vein)	NEW	2.11	1.92	No
9X005	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (eg, from the inferior vena cava)	NEW	2.13	2.04	No
9X015	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes	NEW	1.00	1.00	No
9X016	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; each additional 15 minutes	NEW	0.54	0.54	No
9X017	Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving,	NEW	0.23	0.23	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	safety practices) (without the patient present), face-to-face with multiple sets of caregivers				
9X034	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes	NEW	C	C	No
9X035	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes	NEW	C	C	No
9X036	Pelvic examination	NEW	0.00	0.00	No
9X045	Therapy activation of implanted phrenic nerve stimulator system including all interrogation and programming	NEW	0.85	0.85	No
9X046	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system	NEW	0.80	0.80	No
9X047	Interrogation and programming of implanted phrenic nerve stimulator system during a polysomnography	NEW	1.82	1.82	No
9X048	Interrogation, without programming of implanted phrenic nerve stimulator system	NEW	0.43	0.43	No
9X070	Percutaneous transluminal coronary lithotripsy	NEW	2.97	2.97	No
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval	0.00	0.00	0.00	No
G0323	Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, clinical professional counselor, professional counselor, or marriage and family therapist time, per calendar month.	0.61	-	0.93	Yes
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	0.00	0.00	D	No
G2086	Office-based opioid treatment, monthly bundle including development of the treatment plan, care coordination, substance use counseling, individual therapy, and group therapy; initial month	7.06	-	8.14	Yes
G2087	Office-based opioid treatment, monthly bundle including care coordination, substance use counseling, individual therapy, and group therapy; subsequent month	6.89	-	7.97	Yes
G2211	Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.	B	-	0.33	No
GPFC1	Psychotherapy for crisis furnished in an applicable site of service; first 60 minutes	NEW	-	4.70	No
GPFC2	Psychotherapy for crisis furnished in an applicable site of service; each additional 30 minutes	NEW	-	2.25	No
GXXX1	Community health integration services performed by certified or trained auxiliary personnel, which may include a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are	NEW	-	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit				
GXXX2	Community health integration services, each additional 30 minutes per calendar month	NEW	-	0.70	No
GXXX3	Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, which may include a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities	NEW	-	1.00	No
GXXX4	Principal Illness Navigation services, additional 30 minutes per calendar month	NEW	-	0.70	No
GXXX5	Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes	NEW	-	0.18	No

TABLE 13: CY 2024 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
30117	Removal of intranasal lesion	L037D	RN/LPN/MTA	NF	Conduct patient communications	3	0	G1: See preamble text	-1.49
30117	Removal of intranasal lesion	L037D	RN/LPN/MTA	F	Conduct patient communications	3	0	G1: See preamble text	-1.49
30117	Removal of intranasal lesion	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37
30118	Removal of intranasal lesion	L037D	RN/LPN/MTA	F	Conduct patient communications	3	0	G1: See preamble text	-1.49
3X014	Rmv&rplcmt phrnc nrv stim pg	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	53	L9: Refined clinical labor to align with number of post-operative visits	8.47
3X016	Nsl/sinus ndsc rf abltj pnn	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		39	32	E19: Refined equipment time to conform to established policies for scope accessories	-1.87
3X016	Nsl/sinus ndsc rf abltj pnn	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37
3X017	Nsl/sinus ndsc cryoabltj pnn	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		39	34	E19: Refined equipment time to conform to established policies for scope accessories	-1.34
3X017	Nsl/sinus ndsc cryoabltj pnn	ES040	PROXY endoscope, rigid, sinoscopy (0 degrees)	NF		39	41	E4: Refined equipment time to conform to established policies for scopes	0.02
3X017	Nsl/sinus ndsc cryoabltj pnn	SB027	gown, staff, impervious	NF		2	0	S1: Duplicative; supply is included in SA042	-2.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
5X005	Transcrv abltj utrn fibrd rf	EQ138	instrument pack, medium ($1500 and up)	NF		65	77	E5: Refined equipment time to conform to established policies for surgical instrument packs	0.08
64590	Ins/rpl prph sac/gstr npgr	EQ114	electrosurgical generator, up to 120 watts	NF		56	48	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.14
64590	Ins/rpl prph sac/gstr npgr	EQ209	programmer, neurostimulator (w-printer)	NF		56	84	E7: Refined equipment time to conform to office visit duration	0.18
76882	Us lmtd jt/fcl evl nvasc xtr	ED053	Professional PACS Workstation	NF		14	17.5	E18: Refined equipment time to conform to established policies for PACS Workstations	0.21
76882	Us lmtd jt/fcl evl nvasc xtr	EQ250	ultrasound unit, portable	NF		23	15	E11: Refined equipment time to conform with other codes in the family	-1.29
7X005	N-invas est c ffr sw aly cta	ED053	Professional PACS Workstation	NF		14.5	13.5	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.06
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Prepare room, equipment and supplies	1.5	0.5	G1: See preamble text	-0.64
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	1	0.5	G1: See preamble text	-0.32
G0277	Hbot, full body chamber, 30m	L047C	RN/Respiratory Therapist	NF	Perform procedure/service---NOT directly	30	15	G1: See preamble text	-9.65

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					related to physician work time				

TABLE 14: CY 2024 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
3X014	Rmv&rplcmt phrnc nrv stim pg	EF023	table, exam	F		36	53	E15: Refined equipment time to conform to changes in clinical labor time	0.18
G0277	Hbot, full body chamber, 30m	EQ131	hyperbaric chamber	NF		40	23.25	E15: Refined equipment time to conform to changes in clinical labor time	-3.90
G0277	Hbot, full body chamber, 30m	EQ362	HBOT air break breathing apparatus demand system (hoses, masks, penetrator, and demand valve)	NF		40	23.25	E15: Refined equipment time to conform to changes in clinical labor time	-0.04

TABLE 15: CY 2024 Invoices Received for Existing Direct PE Inputs

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
36514	tubing set, plasma exchange	SC085	$186.12	$244.88	32%	2	328
36514, 36516	tubing set, blood warmer	SC084	$8.01	$15.33	91%	2	911
43754, 43755, 43756, 43757, 88120, 88121, 91065	biohazard specimen transport bag	SM008	$0.080	$0.087	9%	1	101,558
65778	human amniotic membrane allograft mounted on a non-absorbable self-retaining ring	SD248	$1,097.91	$872.50	-21%	2	48,005
65779	human amniotic membrane allograft	SD247	$771.33	$835.00	8%	1	106
88104, 88106, 88108, 88112, 88160, 88161, 88162	stain, PAP OG-6	SL491	$0.010	$0.020	100%	1	444,216
88302, 88304, 88305, 88307, 88309, 88312, 88313, 88319, 88323, 88325, 88355, 88358, G0416	slide dryer	EP034	$962.50	$1,785.49	86%	1	13,423,336
88302, 88304, 88305, 88307, 88309, 88341, 88342, 88344, 88360, 88361, G0416	Automated Casette Labeler	EP111	$26,700.26	$31,658.81	19%	1	14,100,742
88313	Congo Red kits	SA110	$6.16	$6.80	10%	1	799,406
88313, 88314	hematoxylin reagent	SL077	$0.0200	$0.0375	88%	1	815,572
88341	Anti CD45 Monoclonal Antibody	SL495	$4.48	$5.15	15%	3	982,692

88341, 88342, 88344, 88360, 88361	E-bar labels (Ventana 1358501)	SL475	$0.72	$1.104	53%	1	2,422,030
88341, 88342, 88344, 88360, 88361	UltraView Universal DAB Detection Kit	SL488	$9.70	$12.28	27%	3	2,422,030
88342	Confirm anti-CD15 Mouse Monoclonal Antibody (Ventana 760-2504)	SL474	$3.82	$4.90	28%	1	1,061,368
88344, 88360, 88361	250 Test Prep Kit # 78 (Ventana 786-3034)	SL486	$0.290	$0.309	7%	2	377,970
92230, 92235, 92242, 92287	fluorescein inj (5ml uou)	SH033	$49.13	$72.00	47%	7	305,201
95145, 95146, 95148, 95149	antigen, venom	SH009	$30.93	$35.58	15%	18	49,334
95147, 95148, 95149	antigen, venom, tri-vespid	SH010	$60.24	$69.21	15%	9	38,269

TABLE 16: CY 2024 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
2X000	Dorsal SI Joint Arthrodesis Implant	SD356	11,500.00	1	0
3X016	Radiofrequency Stylus / wand	SD357	1,950.00	4	3,728
3X016	Radiofrequency console	EQ407	4,972.50	4	3,728
3X017	Cryoablation handpiece and 2 canisters (one per side)	SD358	1,882.80	7	7,501
5X000	Optilume DCB, guidewire, and inflation device	SD359	2,245.00	22	0
5X005	Dispersive electrode (Sonata)	SD360	30.00	1	0
5X005	RFA Handpiece, sterile (Sonata)	SD361	2,500.00	1	0
5X005	RFA Generator System, including probe, cables and sterilization tray (Sonata)	EQ408	118,250.00	2	0
9X045, 9X046, 9X047, 9X048	phrenic nerve stimulator programmer with wand	EQ406	3,008.00	2	156

TABLE 17: CY 2024 No PE Refinements

HCPCS	Description
22857	Tot disc arthrp 1ntrspc lmbr
22860	Tot disc arthrp 2ntrspc lmbr
2X000	Arthrd si jt prq wo tfxj dev
2X002	Ant thrc vrt body tethrg <7
2X003	Ant thrc vrt body tethrg 8+
2X004	Rev rplc/rmv thrc vrt tethrg
3X008	Insj phrnc nrv stim sys
3X010	Rmvl phrnc nrv stim sys
3X011	Rmvl phrnc nrv stim transvns
3X012	Rmvl phrnc nrv stim pg only
3X013	Reposg phrnc nrv stim trnsvn
3X015	Rmv&rplcmt phrnc nrv stim ld
5X000	Cysto rx balo cath urtl strx
619X1	Ins sk-mnt crnl nstm pg/rcvr
619X2	Rev/rplcmt sk-mnt crnl nstm
619X3	Rmv sk-mnt crnl nstm pg/rcvr
63685	Ins/rplcmt spi npgr pocket
63688	Rev/rmv imp spi npgr dtch cn
64595	Rev/rmv prph sac/gstr npgr
64XX2	Ins/rplcmt prq eltrd ra pn 1
64XX3	Ins/rplcm prq eltrd ra pn ea
64XX4	Rev/rmvl nea pn w/intg nstim
65778	Cover eye w/membrane
65779	Cover eye w/membrane suture
65780	Ocular reconst transplant
6X000	Sprchoroidal spc njx rx agt
76881	Us xtr non-vasc complete
76883	Us nrv&acc strux 1xtr compre
76937	Us guide vascular access
7X001	Dx intraop epicar car us chd
926X1	Dx aly aud oi snd prcsr 1st
926X2	Dx aly aud oi snd prcsr each
93297	Icm device interrogat remote
93298	Ilr device interrogat remote
99484	Care mgmt svc bhvl hlth cond
99497	Advncd care plan 30 min
99498	Advncd care plan addl 30 min
9X015	Caregiver traing 1st 30 min
9X016	Caregiver traing ea addl 15
9X017	Group caregiver training
9X036	Pelvic examination
9X045	Therapy activation ipnss
9X046	Interrog&prgrmg ipnss
9X047	Interrog&prgrmg ipnss polysm
9X048	Interrog w/o prgrmg ipnss

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F. Evaluation and Management (E/M) Visits

1. Background

Over the past several years, we have engaged in a multi-year effort with the American Medical Association (AMA) and other interested parties to update coding and payment for evaluation and management (E/M) visits, so that they better reflect the current practice of medicine, are less administratively complex, and are paid more accurately under the PFS. This work is critical to improve payment accuracy and help reduce practitioner burnout.

E/M visits comprise approximately 40 percent of all allowed charges under the PFS. The office/outpatient (O/O) E/M visits comprise approximately half of these allowed charges (approximately 20 percent of total PFS allowed charges), and Other E/M visits (such as inpatient/observation visits, nursing facility visits and home/residence visits) comprise the other half (approximately 20 percent of total PFS allowed charges). As we have discussed in prior rules, within the E/M services represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties (84 FR 62844). According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Accordingly, our policies for revaluation of E/M visits have a significant impact on relative resource valuation under the PFS, which could potentially impact patient care more broadly.

In this section of our proposed rule, we continue our work to address two outstanding issues in E/M visit payment: implementing separate payment for the O/O E/M visit complexity add-on code for separate payment, and our definition of split (or shared) visits which we delayed last year.

For CY 2018, we solicited public comment regarding how we could comprehensively reform the E/M documentation guidelines to reduce administrative and clinical burden, improve payment accuracy, and better align E/M coding and documentation with the current practice of medicine (82 FR 34078–34079, 82 FR 53163). We believed that the documentation requirements for history and physical exam were particularly outdated clinically and that medical decision making (MDM) and time were the more significant factors in distinguishing visit levels (82 FR 53164). Public commenters recommended a transparent, iterative, and perhaps transitional approach, and some commenters suggested that CMS and the AMA should also undertake revision and revaluation of the E/M visit code set itself, in addition to updating the documentation guidelines (82 FR 53165). Having reviewed the public comments, we noted they illustrated how difficult it is to utilize or rely upon such a relatively small set of codes to describe and pay for the work of a wide range of physicians and practitioners in many vastly different clinical contexts; that E/M documentation guidelines were not simply a matter of administrative burden, but were also clinically outdated and intimately related to the definition and description of E/M work as well as valuation; and that there were different opinions on potential redefinition and revaluation of the E/M code set depending on practitioner specialty, and the type of work dominating the specialty (for example, primary care, so-called ''cognitive'' specialty work, or global

procedures that have E/M visits bundled in rather than separately performed and documented) (82 FR 53165). We stated that we would continue working on these issues with interested parties in future years.

Because we agreed with commenters that we should take an incremental approach to these issues, the following year we proposed changes largely limited to the O/O E/M visit code family (83 FR 59628). In our CY 2019 PFS final rule, we finalized documentation changes, some of which took effect in CY 2019 (83 FR 59628–59535), while others (notably choice of MDM or time for supporting documentation) would be effective in CY 2021 in conjunction with finalized coding and payment changes for O/O E/M visits (83 FR 59636–59645). The coding and payment changes included a single payment rate for levels 2 through 4 O/O E/M visits (retaining separate payment for level 5 visits to account for the most complex patients and visits); two HCPCS add-on codes to provide separate, additional payments for the resource costs involved in furnishing certain types of O/O E/M visit care, specifically visit complexity inherently associated with primary care and non-procedural specialty care; and a third HCPCS code for O/O E/M visits taking extended amounts of time (83 FR 59638).

In January–February 2019, we held listening sessions, and we learned that the AMA was convening an E/M Workgroup to develop an alternative solution to some of these issues (84 FR 40673). The AMA proceeded to revise and resurvey the O/O E/M visit code family (see 84 FR 62844 through 62847). Effective January 1, 2021, the CPT Editorial Panel redefined the codes for O/O E/M visits such that the furnishing practitioner may select the level of visit to bill based either on the amount of practitioner time spent performing the visit or the level of medical decision-making (MDM) involved. The CPT Editorial Panel redefined MDM in the CPT E/M Guidelines, which are an accompanying set of CPT interpretive guidelines delineating different levels of MDM and various other reporting parameters. Additionally, history of present illness (History) and a physical exam were no longer used to select the O/O E/M visit level. These service elements were updated to remove reliance on clinically outdated parameters to contribute to selection of visit level, such as number of body systems reviewed, and to require instead that a medically appropriate history and exam are performed. Also, effective January 1, 2021, the CPT Editorial Panel revised the O/O E/M visit descriptor times. Previously, the CPT code descriptors included typical service times, but they were revised to specify new time ranges that must be furnished in order to select a given visit level using time. The AMA RUC resurveyed the O/O E/M visit CPT codes, and provided us with revaluation recommendations that we then addressed in our CY 2020 PFS proposed rule, a year in advance of when the revised codes would take effect in CY 2021 (84 FR 40675 through 40678).

In our CY 2020 PFS final rule, we generally adopted the revised O/O E/M code set and the related changes in the CPT E/M Guidelines, including the revised approach to visit level selection and documentation, for payment purposes under the PFS effective January 1, 2021 (84 FR 62844 through 62859). While we accepted the revised CPT codes and approach for the O/O E/M visits, we finalized Medicare-specific coding for prolonged O/O service codes, because we were concerned that the CPT codes were administratively complex, and their use would have impacted our ability to tell how much total time was spent with the patient and could have resulted in inappropriately inflated payment (84 FR 62849 through 62850, and 85 FR 84572 through 84575).

In our CY 2020 PFS final rule, we generally accepted the RUC recommendations, which reflected increased service times (84 FR 62851 through 62854). This resulted in increased values for the O/O E/M visit codes beginning in CY 2021. However, since we believed these increased valuations still did not account for the resources involved in furnishing certain kinds of care included in the O/O E/M visit code set, in the CY 2021 PFS final rule, we retained our add-on codes for visit complexity inherently associated with primary care and non-procedural specialty care, though we refined and consolidated them into a single code, a HCPCS add-on code G2211 (*O/O E/M visit complexity*) that can be reported in conjunction with O/O E/M visits to better account for additional resources associated with primary care, or similarly ongoing medical care related to a patient's single, serious condition, or complex condition (84 FR 62854 through 62856, 85 FR 84571). (Hereafter in this rule, we refer to this code as the O/O E/M visit complexity add-on).

After we issued the CY 2021 PFS final rule, section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) (CAA, 2021) imposed a moratorium on Medicare payment for this service by prohibiting CMS from making payment under the PFS for services described by HCPCS code G2211 (or any successor or substantially similar code) before January 1, 2024. Accordingly, the O/O E/M visit complexity add-on code can be reported, but it is currently assigned a bundled payment status indicator. See our fact sheet available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet [30] (*cms.gov*).

In the CY 2022 PFS final rule, we established revised payment rules for split (or shared) visits (86 FR 65150 through 65159). The following year the CPT Editorial Panel defined a split (or shared) visit for the first time in the CPT E/M Guidelines for 2023. However, we did not adopt the CPT definition as it did not conform with our established final policy or address which practitioner should report a shared visit.

For CY 2023, the CPT Editorial Panel also revised the rest of the E/M visit code families (except critical care services) to match the general framework of the O/O E/M visits, including inpatient and observation visits, emergency department (ED) visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment. We refer to these other E/M visit code families as ''Other E/M'' visits or CPT codes, as relevant. Effective January 1, 2023, the CPT Editorial Panel redefined the Other E/M visits so that they parallel the O/O E/M visits, where visit level is selected based on the amount of practitioner time spent with the patient or the level of MDM as redefined in the CPT E/M Guidelines. As for the O/O E/M visits, a medically appropriate history and/or physical exam is a required element of the services, but no longer impacts the Other E/M visit level. The CPT Editorial Panel also revised the service times within the descriptors, the associated CPT prolonged service codes, and the CPT E/M Guidelines for the Other E/M CPT codes. The CPT Editorial Panel also consolidated a considerable number of the Other E/M CPT codes, with inpatient and observation visits being combined into a single code set, and home and domiciliary visits being combined into a single code set. The CPT Editorial Panel created one new CPT code for prolonged inpatient services by physicians and other qualified healthcare professionals on the date of the E/M visit. Finally, the RUC resurveyed the Other E/M visits and associated prolonged service codes,

[30] *https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf.*

and provided revaluation recommendations to CMS.

We addressed all of these changes to the Other E/M visit families in the CY 2023 PFS final rule (87 FR 69586 through 69616). In that final rule, we adopted the revised CPT codes and descriptors for Other E/M visits, except for prolonged services for which we finalized Medicare-specific coding. We also adopted the CPT E/M Guidelines for levels of MDM as revised for 2023. Regarding valuation, we adopted most of the RUC-recommended values for Other E/M visits, which increased their relative valuation in aggregate. However, we stated our belief that certain types of O/O E/M visits remain undervalued, given the moratorium on separate payment for the O/O E/M visit complexity add-on (87 FR 69588).We expressed concern about assumptions made in the RUC recommendations for Other E/M visits that patient needs were inherently more complex, or work was more intense for E/M visits furnished in non-office settings (for example, inpatient, ED, and home settings) when compared to the office settings (87 FR 69587 through 69588). We stated that this direct comparison between Other E/M visits and the O/O E/M visit codes may not be appropriate or accurate, and laid out reasons why practitioners in office settings may expend more resources than practitioners in institutional and other settings. We note that the survey times for O/O E/M visits increased significantly when resurveyed (85 FR 50123), while times for Other E/M visits generally decreased significantly or remained the same when resurveyed, despite the level of MDM remaining constant (87 FR 69598, 69605). To the extent we adopted the RUC-recommended values for Other E/M visits beginning in CY 2023, we expressed that we did not agree that the RUC-recommended relative values for E/M visits fully accounted for the complexity of certain kinds of visits, especially for those in the office setting, nor do they fully reflect appropriate relative values, since separate payment is not yet made for the O/O E/M visit complexity add-on (87 FR 69588).

During the CAA, 2021 moratorium on separate payment for the O/O E/M visit complexity add-on, interested parties have continued to engage CMS about the appropriate valuation of O/O E/M visits relative to other PFS services, including through public comments on the proposed revaluation of Other E/M visits (87 FR 70218), as well as in meetings and letters submitted to CMS outside of the rulemaking process. Anticipating the end of the CAA, 2021 moratorium, interested parties including the AMA, several medical associations, and others recently approached CMS outside of the rulemaking process with recommendations regarding implementation and potential refinements to the service beginning in 2024 to ensure the appropriate relative valuation of O/O E/M visits. Interested parties have also continued to approach CMS and the CPT Editorial Panel with questions and recommendations about payment rules for split (or shared) visits.

2. Office/Outpatient (O/O) E/M Visit Complexity Add-On Implementation

a. Background

As discussed above, in the CY 2021 PFS final rule, CMS refined the O/O E/M visit complexity add-on code, GPC1X (which was replaced by HCPCS code G2211), to describe intensity and complexity inherent to O/O E/M visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition. (85 FR 84569–84571). While we adopted the AMA RUC recommendations for the revised O/O E/M CPT visit codes, those values did not fully account for the resource costs associated with primary care and other longitudinal care of complex patients. Under our final policy, which was delayed by the CAA, 2021 before it was implemented, the O/O E/M visit complexity add-on code could be reported with all O/O E/M visit levels. We disagreed with comments suggesting that billing of the O/O E/M visit complexity add-on code should be restricted to higher level office/outpatient E/M visits; and responded that, given the wide variety of visit types billable with the office/outpatient E/M visit code set, we did not believe that the value associated with the typical visit accounts for the additional resources associated with primary care or ongoing care related to a patient's single, serious, or complex chronic condition, regardless of the visit level. The full descriptor for the O/O E/M visit complexity add-on code, as refined in the CY 2021 PFS final rule, is HCPCS code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established))* (85 FR 84571) We also estimated that the O/O E/M visit complexity add-on service would be reported by specialties that rely on office/outpatient E/M visits to report the majority of their services and would be billed in addition to those E/M visits. While we did not explicitly prohibit billing the O/O E/M visit complexity add-on in conjunction with visits that are reported with various modifiers, and did not exclude those from our utilization estimates, we stated we did not expect the add-on service to be reported for visits billed with a payment modifier, for example, to identify a separately billable E/M visit in conjunction with a minor procedure (85 FR 84571 through 84572).We stated that visits reported with payment modifiers are likely to involve resources that are distinct from the stand-alone O/O E/M visits for primary care and other longitudinal care of complex patients, and that we may consider this issue in potential future rulemaking. We further stated that we do not expect the O/O E/M visit complexity add-on code to be reported when the O/O E/M visit is reported with payment modifiers such as modifier-25 which describes separately billed visits on the same day as another visit or procedure (see our fact sheet, identifying additional modifiers, available at Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits—Fact Sheet (*cms.gov*)).

Interested parties have continued to express uncertainty about when it would be appropriate to report the O/O E/M visit complexity add-on service. Some interested parties have expressed larger concerns about potential reductions to the PFS CF or redistributive impacts among specialties if we were to implement the O/O E/M visit complexity add-on code. In the CY 2021 PFS final rule, we clarified and refined the service definition to alleviate some of these concerns and revised our utilization estimates (85 FR 84572). Conversely, some interested parties, specifically practitioners that rely on office/outpatient E/M visits to report the majority of their services, who could use the add-on code to better reflect the resources they use to furnish complex longitudinal services expressed continued support for our policy. We reiterated our belief that the O/O E/M visit complexity add-on reflects the time, intensity, and PE resources involved when practitioners furnish the kinds of O/O E/M office visit services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a

chronic condition or single high-risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time. In response to comments, we also made further refinements to the HCPCS code descriptor to clarify that the code applies to a serious condition rather than any single condition. We also acknowledged concerns that, given the request by some medical societies for additional time to educate their members about appropriate use of the O/O E/M visit complexity add-on code, ongoing implementation of the revisions to the O/O E/M visit code set, electronic health records integration, and the persistence of the COVID–19 pandemic, practitioners that rely on O/O E/M visits to report the majority of their services are not likely to report the complexity add-on code with every office visit. However, we disagreed with commenters who thought the O/O E/M visit complexity add-on code would be billed with only 10 to 25 percent of O/O E/M services. Because we had not implemented any additional policies that restricted the billing of this code, we estimated that the add-on code would be billed with 90 percent of O/O E/M visits billed by certain physician specialties (roughly 58 percent of all office/outpatient E/M visits).

b. Proposal for O/O E/M Visit Complexity Add-On HCPCS Code G2211

Interested parties have continued to engage with us and provide recommendations for implementation of the O/O E/M visit complexity add-on. Some commenters recommended that CMS delay the implementation of HCPCS add-on code G2211, citing concerns about the expected budget neutrality adjustment necessitated by implementation of the O/O E/M visit complexity add-on and redistributive impact on PFS payment (85 FR 84572). Many commenters who rely upon O/O E/M visits to report the majority of their services continued to be supportive of HCPCS add-on code G2211 (85 FR 84570) and have recommended that we speedily implement it. Some of these commenters also recommended ways to clarify the intended use of the O/O E/M visit complexity add-on code, which could reduce redistributive impacts. Finally, as noted above, the values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with a policy that would have provided separate payment for the new add-on code G2211 (87 FR 69588).To the extent we adopted the RUC-recommended values for Other E/M visits beginning in CY 2023, we expressed that we did not agree that the RUC-recommended relative values for E/M visits fully reflected appropriate relative values, since separate payment is not yet made for HCPCS code G2211.

The CAA, 2021 moratorium on Medicare payment under the PFS for HCPCS code G2211 will end on December 31, 2023. We are proposing to change the status of HCPCS code G2211 to make it separately payable by assigning the ''active'' status indicator, effective January 1, 2024. After considering feedback we have received from interested parties, both through the CY 2021 PFS rulemaking process and during the moratorium, we are also proposing several policy refinements (with respect to HCPCS code G2211). We stated in the CY 2021 PFS final rule that we would not expect HCPCS add-on code G2211 to be reported when the O/O E/M service is reported with a payment modifier, such as the modifier-25, which denotes a separately billable E/M service by the same practitioner furnished on the same day of a procedure or other service (85 FR 84572). We continue to believe that separately identifiable O/O E/M visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant different payment (85 FR 84572). As such we are proposing that the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25.

Interested parties have also requested that we reconsider our previous utilization assumptions. In the CY 2021 PFS final rule, we had assumed that specialties that rely on O/O E/M visit codes to report the majority of their services would be most likely to report the O/O E/M visit complexity add-on code, and that they would report the add-on code with every O/O E/M visit they report. We acknowledged commenters' concerns that, given the request by some medical societies to educate their members about appropriate use, and ongoing implementation of the revisions to the office/outpatient E/M visit code set, and electronic health records integration, practitioners that rely on office/outpatient E/M visits to report the majority of their services would not be likely to report HCPCS code G2211 with every O/O E/M visit they report (85 FR 84572).

Interested parties have presented reasons we find persuasive that such practitioners would not be likely to report HCPCS code G2211 with every O/O E/M visit they report. They reasoned that many practitioners delivering care in settings specifically designed to address acute health care needs, without coordination or follow-up, will regularly have encounters with patients that are not part of continuous care.

Furthermore, in contrast to situations, where the patient's overall, ongoing care is being managed, monitored, and/or observed by a specialist for a particular disease condition, we continue to believe that there are many visits with new or established patients where the O/O E/M visit complexity add-on code would not be appropriately reported, such as when the care furnished during the O/O E/M visit is provided by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature; such as, but not limited to, a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus; for counseling related to seasonal allergies, initial onset gastroesophageal reflux disease; treatment for a fracture; and where comorbidities are either not present or not addressed, and/or when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time (85 FR 84570 and 84571).

These considerations taken together with our proposal that the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25 have informed our revised utilization assumptions. Taking into consideration the comments received by interested parties, and the reasons discussed above, we now estimate that HCPCS code G2211 will be billed with 38 percent of all O/O E/M visits initially. We calculated these revised utilization assumptions by considering the uptake of new codes in prior years, and the O/O E/M billing patterns of all specialties. Specifically, we took into account the likelihood that primary care specialties will have a higher utilization of the add-on code than other specialties, surgical specialties will have the lowest utilization since they are less likely to establish longitudinal care relationships with patients, and other specialists are more likely to have longitudinal care

relationships than surgical specialties but less likely than primary care specialists. We also revised our estimates by excluding (1) claims from practitioners participating in CMS capitated models, and (2) claims for established patient visits performed by certain specialties that are unlikely to have a longitudinal care relationship with a beneficiary. We also accounted for the proportion of visits billed that were furnished as consults or for the purpose of obtaining a second clinical opinion and excluded these types of visits from our estimates. We estimate that when fully adopted, HCPCS code G2211 will be billed with 54 percent of all O/O E/M visits. This fully adopted estimate is informed by considering uptake of new codes after several years. We seek comment on these utilization assumptions and the application of this proposed policy for CY 2024.

c. Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

Over the last several years, we have received suggestions/recommendations outside of the rulemaking process that CMS consider using a different approach for valuing services that relies on research and data other than the AMA RUC's specialty-specific valuation recommendations. These commenters have highlighted that the evolving practice of medicine looks significantly different than it did when the resource-based relative value scale (RBRVS) was established three decades ago. Disease prevention and health promotion have grown in practice and patient expectations are higher for the management of hypertension, diabetes, and hypercholesterolemia. Additionally, more pharmaceuticals and new biologics have expanded therapeutic options for non-procedural care. Commenters have suggested convening expert panels that might review pertinent research and recommend resource recalibrations for purposes of updating relative values under the PFS. The commenters suggested that such independent assessments could support CMS and the broader health delivery and health finance community in addressing growing distortions in resource allocations under the PFS for certain types of services, including evaluation and management visits and other non-procedural/non-surgical services.

For many years, CMS has worked to address coding and payment deficiencies, explicitly focusing on instances where resources are not well accounted for in the inputs for certain services, including where significant differences in relative resources involved in furnishing care are not reflected in the coding distinctions, or where too-specific coding makes valuation at appropriate intervals impractical. As we continue ongoing work to establish resource-based relative units for PFS services, we also seek public comment about the potential range of approaches CMS could take to improve the accuracy of valuing services. We are especially interested in how we might improve the accuracy of valuation for services, and we are seeking information about how we might evaluate E/M services with greater specificity, more regularly and comprehensively.

As we consider how CMS can potentially move forward with reforms to the way we establish values for E/M and other services, we are particularly interested in receiving comments from the public on the following questions:

a. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?

b. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?

c. Are the current Non-E/M HCPCS codes accurately defined?

d. Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?

e. What are the consequences if services described by HCPCS codes are not accurately defined?

f. What are the consequences if services described by HCPCS codes are not accurately valued?

g. Should CMS consider valuation changes to other codes similar to the approach in section II.J.5. of this rule?

We are particularly interested in ways that CMS could potentially improve processes and methodologies, and we request that commenters provide specific recommendations on ways that we can improve data collection and to make better evidence-based and more accurate payments for E/M and other services. We are particularly interested in recommendations on ways that we can make more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines and new technologies that represent standards of care. We are also interested in recommendations that would ensure that data collection from, and documentation requirements for, physician practices are as least burdensome as possible while also maintaining strong program integrity requirements. Finally, we are also interested in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide recommendations to CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations.

3. Split (or Shared) Visits

The split (or shared) ''substantive portion'' policy for services furnished in facility settings was reflected in subregulatory guidance until it was withdrawn in May 2021, in response to a petition under the, since rescinded, Good Guidance regulation (see 87 FR 44002 (February 25, 2022). In the CY 2022 PFS final rule (86 FR 65150 through 65159), we finalized a policy for evaluation and management (E/M) visits furnished in a facility setting, to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and non-physician practitioner (NPP) provide the service together (not necessarily concurrently) and the billing physician personally performs a substantive portion of the visit. Commenters were generally supportive of our CY 2022 proposals; however, there were divided comments with regard to our proposed definition of ''substantive portion.'' Some commenters preferred the use of medical decision making (MDM) or one of the three key visit components as opposed to time for purposes of defining the ''substantive portion'' of the service.

a. Background

A split (or shared) visit refers to an E/M visit performed by both a physician and an NPP in the same group practice. In the non-facility (for example, office) setting, the rules for ''incident to'' billing apply under this circumstance. However, ''incident to'' services are not available for services furnished in a facility setting. Longstanding CMS policy has been that, for split (or shared) visits in the facility (for example, hospital) setting, the physician can bill for the services if they perform a substantive portion of the encounter. Otherwise, the NPP would bill for the service. Section 1833(a)(1)(N) of the Act specifies that payment is made for services furnished and billed by a physician at 100 percent of the PFS rate, while under section 1833(a)(1)(O)(i) of the Act, certain NPPs are paid for the services they furnish and bill for at a reduced PFS rate (85 percent of the PFS).

For CY 2023, after considering the public comments we received, we finalized that we would delay implementation of our definition of the

substantive portion as more than half of the total practitioner time until January 1, 2024. We defined ''substantive portion'' in the CY 2022 PFS final rule (86 FR 65152 through 65156) and provided for billing of split (or shared) visits in certain settings (86 FR 65156 through 65157) and for certain patient types (new and established) (86 FR 65156). After consideration of the public comments on the CY 2022 PFS proposed rule, we finalized a phased-in approach to this policy (86 FR 65153). For CY 2022, we finalized the definition of ''substantive portion'' as one of the following: either one of the three key E/M elements (that is, history, exam, or MDM) or more than half of total time. We also stated that we would delay the full implementation of the definition of ''substantive portion'' as more than half of total time until CY 2023 (86 FR 65152 and 65153).

Additionally, in the CY 2022 PFS final rule (86 FR 65158 through 65159), we finalized our proposal to create a payment modifier (modifier FS), to describe split (or shared) visits (see 86 FR 65158 through 65159 for this discussion). Over time, implementing and using this modifier will better enable us to quantify split (or shared) visits and better understand the billing patterns of practitioners that typically furnish them. Such information is helpful to CMS for program integrity purposes and may also inform us on whether we need to clarify or further revise the policy for these services in future rulemaking. To date, we have roughly one year's worth of claims data from the time the modifier was instituted as part of our ongoing engagement with interested parties. We have continued to hear concerns about our intent to implement our policy to use more than half of the total time to define the ''substantive portion'' of a split or shared visit, and have received requests to continue to recognize MDM as the ''substantive portion.'' Many of these concerns specifically reference disruptions to current team-based practice patterns, and the potential for significant adjustments to the practice's internal processes or information systems to allow for tracking visits based on time, rather than MDM. With these concerns in mind, in the CY 2023 PFS final rule (87 FR 69614 through 69616), we finalized a policy to delay implementation of our definition of substantive portion as more than half of the total practitioner time until January 1, 2024.

After much consideration, we are proposing to delay the implementation of our definition of the ''substantive portion'' as more than half of the total time through at least December 31, 2024 for the same reasons outlined in the CY 2023 PFS final rule (87 FR 69614 through 69616). We are proposing to maintain the current definition of substantive portion for CY 2024 that allows for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit. This proposed additional delay allows interested parties to have another opportunity to comment on this policy, and gives CMS time to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of our policy. We are interested in how facilities are currently implementing our split (or shared) services policy in their workflows and how facilities are currently accounting for services of billing practitioners that are performed split (or shared). We are also interested in how to better account for the services of the billing practitioner in team-based care clinical scenarios. We understand that the AMA CPT Editorial Panel is considering revisions to aspects of split or shared visits that may impact our policies, but those changes may not be finalized before this proposed rule is published. We will review the AMA CPT Editorial Panel's changes to split or shared visits when and if available before the final rule and in the context of our policy proposal. We will consider any changes that are made and their relationship to our previously finalized policies, and whether a further implementation delay beyond CY 2024 or revision of the definition of substantive portion is warranted. We would address any changes through future rulemaking.

We are proposing to amend 42 CFR 415.140 to revise the definition of ''substantive portion'' in the interim while we continue to analyze and collect information from interested parties and commenters as to whether we should permanently modify our current definition. We note the current definition of ''substantive portion'' applies for visits other than critical care visits furnished in CY 2022 through CY 2024. We are amending § 415.140 by removing ''the year 2022 and 2023'' and adding in its place ''years 2022 through 2024'' after the phrase ''For visits other than critical care visits furnished in calendar.'' Therefore, the proposed paragraph would specify, for visits other than critical care visits furnished in calendar years 2022 through 2024, *substantive portion* means either one of the three key components (history, exam, or MDM) or more than half of the total time spent by the physician and NPP performing the split (or shared) visit.

G. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires CMS to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs for the purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2024. Congress recently extended the 1.0 work GPCI floor only through December 31, 2023, in division CC, section 101 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, enacted December 27, 2020). Therefore, the CY 2024 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. See Addenda D and E to this proposed rule for the CY 2024 GPCIs and summarized GAFs. These Addenda are available on the CMS website under the supporting documents section of the CY 2024 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

2. Review of the California Fee Schedule Areas Used for Payment for CY 2024

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, April 1, 2014) added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-State fee schedule area. The resulting modifications to California's locality structure increased its number of fee schedule areas from 9 under the previous locality structure to 27 under the MSA-based locality structure;

although for the purposes of payment, the actual number of fee schedule areas under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational decision.

Section 1848(e)(6)(D) of the Act defined transition areas as the counties in fee schedule areas for 2013 that were in the rest-of-State locality, and locality 3, which was comprised of Marin, Napa, and Solano counties. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the PFS locality structure that was in place prior to CY 2017. That is, the GPCI values applicable for these areas during this transition period were a blend of what the GPCI values would have been for California under the locality structure that was in place prior to CY 2017, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represented the fourth year of the transition period, the applicable GPCI values for counties that were previously in the rest-of-State locality or locality 3 and are now in MSAs were a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the locality structure that was in place prior to CY 2017. The proportions continued to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas were a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the locality structure that was in place prior to CY 2017. Beginning in CY 2022, the applicable GPCI values for counties in transition areas were the values calculated solely under the new MSA-based locality structure; therefore, the phase-in for transition areas is complete. Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless requirement for transition areas beginning with CY 2017; whereby, the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the locality structure that was in place prior to CY 2017. There are 58 counties in California, 50 of which were in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that were not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties. We note that while the phase-in for transition areas is no longer applicable, the hold harmless requirement is not time-limited, and therefore, is still in effect.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, in the CY 2017 PFS final rule (81 FR 80266), we finalized the policy to start by calculating the national GPCIs as if the fee schedule areas that were in place prior to CY 2017 are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach to applying the hold harmless requirement is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is made for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

a. Refinement to Number of Unique Fee Schedule Areas in California for CY 2024

In the CY 2020 final rule (84 FR 62622), a commenter indicated that some of the distinct fee schedule areas that were used during the period between CY 2017 and CY 2018 are no longer necessary. Specifically, with regard to the Los Angeles-Long Beach-Anaheim MSA, which contains 2 counties (across two unique locality numbers, 18 and 26) that are not transition areas, we acknowledge that we only needed more than one unique locality number for that MSA for payment purposes in CY 2017, which was the first year of the implementation of the MSA-based payment locality structure. Neither of the counties in the Los Angeles-Long Beach-Anaheim MSA (Orange County and Los Angeles County) are transition areas under section 1848(e)(6)(D) of the Act. Therefore, the counties were not subject to the aforementioned GPCI value incremental phase-in (which is no longer applicable) or the hold-harmless provision at section 1848(e)(6)(C) of the Act. Similarly, the San Francisco-Oakland-Berkeley MSA contains four counties—San Francisco, San Mateo, Alameda, and Contra Costa counties—across three unique locality numbers, 05, 06, and 07. These counties are not transition areas and will receive the same GPCI values, for payment purposes, going forward. In response to the comment, we acknowledged that we did not propose any changes to the number of fee schedule areas in California, but would consider the feasibility of a technical refinement to consolidate into fewer unique locality numbers; and if we determined that consolidation was operationally feasible, we would propose the technical refinement in future rulemaking. This refinement would ultimately change the number of distinct fee schedule areas for payment purposes in California from 32 to 29. In the CY 2023 PFS proposed rule (87 FR 46008), we proposed to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, thus retiring locality number 26, as it is no longer needed. Similarly, we proposed to identify the San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to three, thus retiring locality numbers 06 and 07, as they are no longer needed. Additionally, we noted that we would modify the MSA names as follows: the San Francisco-Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty), and Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty). We noted that because Marin County is in a transition area and subject to the hold harmless provision at section 1848(e)(6)(C) of the Act, we needed to retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52. Based on support from commenters in the CY 2023 PFS final rule (87 FR 69621), we finalized to identify the Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, and the San

Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as proposed. We noted that, while we believed these changes were appropriate to consolidate fee schedules areas that are no longer operationally necessary, we were unable to operationalize these changes for CY 2023 due to timing constraints relating to the actions and coordination with the various systems maintainers required to effectuate changes to claims processing (87 FR 69621). Therefore, for CY 2023, there were no changes to the existing locality numbers 05, 06, 08, 18, or 26. We noted in the CY 2023 PFS final rule that we would operationalize these finalized changes for CY 2024. We reiterate here that we are operationalizing these locality number changes for CY 2024 via instruction to the MACs, and therefore, locality numbers 06, 07, and 26 will no longer be used for the PFS starting January 1, 2024. We note that these changes, when operationalized, do not have any payment implications under the PFS because these counties are not transition areas and will receive the same GPCI values, for PFS payment purposes, going forward.

H. Payment for Skin Substitutes

1. Background

In the CY 2023 PFS proposed rule, CMS outlined several objectives related to refining skin substitute policies under Medicare, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal-based material, to incorporate more consistent payment methodologies; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. When considering potential changes to policies involving skin substitutes, we noted that we believe it would be appropriate to take a phased approach over multiple rulemaking cycles to examine how we could appropriately incorporate skin substitutes as supplies under the PFS ratesetting methodology. We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

Similar to how we assess costs for other incident to supplies, our approach to identifying appropriate PE direct costs for skin substitute products may include: reviewing various sources for price information, including performing market research, reviewing invoices submitted by interested parties, or reviewing cost information on Medicare claims. Further, we would assess how the incident to supplies are billed or represented while also considering the service with which it is typically furnished. For example, if the supply is billed separately, with the base service, or usually bundled and incident to the base service. Also, we would consider whether there are different supply costs or other meaningful stratifications (for example, a unit of measure or product type) that should be accounted for as we develop direct PE costs, considering how the base service is furnished.

We are soliciting comments on how best to use these approaches under our PFS ratesetting methodology as potential methods to establish appropriate payment for skin substitute products under the PFS.

2. Sources of Price Information

We have refined specific PE data inputs in recent years, using market research and publicly available data (for example, market research on medical supply and equipment items and BLS data to update clinical labor wages) to update the direct PE data inputs used in the PFS ratesetting process. Historically, under the PFS, various sources of information have helped inform payment for specific services used to establish direct PE inputs. Direct PE inputs may derive from assessing the current value of products on the market, which may be achieved by utilizing Average Sales Price (ASP) data or Wholesale Acquisition Cost data (WAC). Since some manufacturers self-report ASP/WAC data at the end of every quarter, this may help to inform CMS of the current market value of these products.

We also review submitted invoices, which reflect the specific cost of products that practitioners are paying manufacturers for these products. We note in the CY 2011 PFS final rule (75 FR 73205) we update supply and equipment prices through an invoice submission process. In this process, we consider the invoice information and incorporate it into our direct costs database if the submitted pricing data indicates the typical market price of the supply or equipment item.

While performing market research and the invoice submission process are different methods to derive pricing for specific products, reviewing cost information on Medicare claims may also help us identify the variability in product costs. For example, assessing detailed cost information on claims with skin substitute products could inform how these products are priced and allow us to consider how the skin substitutes are typically furnished and where these services are performed. This information would enable us to refine our payment policies for these products across different care settings.

We seek comment on the various cost-gathering approaches discussed above that could inform how we establish direct PE inputs for skin substitute products and appropriately develop payment rates for physician services that involve furnishing skin substitute products.

3. Approaches to Billing

We acknowledge that there are various approaches that we could use to identify and establish direct cost inputs for the skin substitute products. We are also considering how to account for these products' variability and resource costs, especially as new products increasingly become available.

Similar to how different sources of information can influence cost information for supplies, specifically considering variables such as different units of measurement, product type, product composition, or in what clinical circumstances the product is used, for example, would help us appropriately reflect costs in payment for the services that include the specific supply. We believe this to be pertinent to how we propose to pay for skin substitute products. For instance, grouping the direct costs for particular skin substitute products based on the typically associated application procedure could help us systematically incorporate the resource costs involved for different product billing scenarios. This approach can be seen in the Outpatient Prospective Payment System (OPPS), where a high-cost/low-cost system is used for skin substitute products billed with a specific procedure code based on their cost grouping.

Alternatively, when services and products are not performed frequently enough to be grouped, retaining separate procedure coding can help inform specificity and granularity for coding

and payment of these services. Specifically, we could create separate procedure coding for specific product types, which could be billed with the appropriate skin substitute application services. We would account for cost variability for the different products (that is, establishing individual or group direct cost profiles and allocating direct costs inputs based on these groupings) under any combination of approaches discussed above. We could also review the unit of measurement for billed products, as available in our internal data or received in submissions, and create direct cost groupings for the products based on the reviewed/billed units of measurement. We could also establish direct cost inputs by employing our standard 'crosswalk' method using information from interested parties. Specifically, we would derive PE inputs by reviewing similarly resourced services to establish RVUs for a service that includes the cost of the skin substitute products and other information to account for the physician's work in furnishing the skin substitute product. We would employ this method to establish payment for individual services that include specific skin substitute products or services that describe cost groupings of similarly priced skin substitute products. As we have discussed in prior rulemaking, we believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. There is a long history of using crosswalk codes for this kind of valuation under the PFS, which is generally established through notice and comment rulemaking.

We seek comment on how these methods discussed above may help reflect the resource costs involved with skin substitute products as furnished with different skin application procedures.

I. Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT Telehealth Services

1. Supervision of Outpatient Therapy Services in Private Practices

(a) Remote therapeutic monitoring for physical therapists and occupational therapists in private practice.

In the CY 2023 PFS final rule, we finalized new policies that would allow Medicare payment for remote therapeutic monitoring (RTM) services, including allowing any RTM service to be furnished under our general supervision requirements (87 FR 69649). RTM refers to the use of devices to monitor a patient's health or response to treatment using non-physiological data (please see more detailed list of RTM services at section II.D. of this proposed rule). The current regulations, however, at §§ 410.59(a)(3)(ii) and 410.60(a)(3)(ii) specify that all occupational and physical therapy services are performed by, or under the direct supervision of, the occupational or physical therapist, respectively, in private practice. These regulations make it difficult for physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs) to bill for the RTM services performed by the physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) they are supervising, since the PTPP or OTPP must remain immediately available when providing direct supervision of PTAs and OTAs (even though we noted in the CY 2022 PFS final rule that PTPPs and OTPPs were intended to be among the primary billers of RTM services (86 FR 65116)). We designated the RTM codes as ''sometimes therapy'' codes (originally in the CY 2022 PFS final rule (86 FR 65116)), meaning that these services may be furnished outside a therapy plan of care when they are performed by physicians and certain NPPs where their State practice includes the provision of physical therapy, occupational therapy, and/or speech-language pathology services. Because we did not propose revisions to §§ 410.59 and 410.60 last year for OTPPs and PTPPs, we are proposing to establish an RTM-specific general supervision policy at §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow OTPPs and PTPPs to provide general supervision only for RTM services furnished by their OTAs and PTAs, respectively.

We also note that Medicare requires each therapist in private practice to meet the requirements specified in our current regulations at §§ 410.59(c) and 410.60(c) to qualify under Medicare as a supplier of outpatient occupational therapy or physical therapy services. Given that occupational therapists (OTs) and physical therapists (PTs) who are not enrolled and working as employees of OTPPs or PTPPs do not meet these requirements, we believe they should continue to function under direct supervision of the OTPP or PTPP. This is consistent with the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 15, section 230.4.B which states that in a private practice, OTPPs and PTPPs must provide direct supervision of all services, including those furnished by OTs and PTs who are not yet enrolled in Medicare (even if they meet the other requirements for occupational therapists and physical therapists at 42 CFR part 484). As such, we are proposing to retain the OTPP and PTPP direct supervision requirement for unenrolled PTs or OTs by clarifying that the proposed RTM general supervision regulation at §§ 410.59(c)(2) and 410.60(c)(2) applies only to the OTA and PTA and does not include the unenrolled OT or PT. We are seeking comment on this specific proposal as we want to know more about how this policy is now functioning with OTs and PTs who are not enrolled and our proposal to maintain this longstanding policy for direct supervision.

We believe this proposal will increase access to these remotely provided services performed by PTAs and OTAs under the general supervision furnished by PTPPs and OTPPs. This aligns the regulatory text at §§ 410.59 and 410.60 with the RTM general supervision policy that we finalized in our CY 2023 rulemaking.

(b) General Supervision for PTs and OTs in Private Practice Comment Solicitation: Sections 1861(p) and 1861(g) (by cross-reference to section 1861(p)) of the Act describe outpatient physical therapy and occupational therapy services furnished to individuals by physical and occupational therapists meeting licensing and other standards prescribed by the Secretary, including conditions relating to the health and safety of individuals who are furnished services on an outpatient basis. The second sentence of section 1861(p) of the Act describes outpatient therapy services that are provided to an individual by a physical therapist or occupational therapist (in their office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, and differentiates the therapists that furnish these outpatient therapy services from those working for an institutional provider of therapy services. In regulations, we have specifically addressed these therapists, previously referred to as PTPPs and OTPPs, since 1999 (63 FR 58868 through 58870). Because we wanted to create consistent requirements for therapists and therapy assistants, we clarified in the CY 2005 PFS final rule with comment period (69 FR 66345) that the personnel qualifications applicable to home health agencies (HHAs) in 42 CFR part 484 are applicable to all outpatient physical therapy, occupational therapy, and speech-language pathology services. Also, in the CY 2005 PFS final rule, we

cross-referenced the qualifications for OTs and their OTAs and PTs and their PTAs for all occupational therapy and physical therapy services, respectively, including those who work in private practices, to 42 CFR part 484 by adding a basic rule at §§ 410.59(a) and 410.60(a), respectively. Under Medicare Part B, outpatient therapy services are generally covered when reasonable and necessary and when provided by PTs and OTs meeting the qualifications set forth at 42 CFR part 484. Services provided by qualified therapy assistants, including PTAs and OTAs, may also be covered by Medicare when furnished under the specified level of therapist supervision that is required for the setting in which the services are provided (institutions, and private practice therapist offices and patient homes).

In accordance with various regulations, the minimum level of supervision for services performed by PTAs and OTAs by PTs and OTs working in institutional settings is a general level of supervision (see Table A in the Report to Congress titled Standards for Supervision of PTAs and the Effects of Eliminating the Personal PTA Supervision Requirement on the Financial Caps for Medicare Therapy Services found at *https://www.cms.gov/Medicare/Billing/TherapyServices/Downloads/61004ptartc.pdf*). For example, 42 CFR 485.713 specifies that when an OTA or PTA provides services at a location that is off the premises of a clinic, rehabilitation agency, or public health agency, those services are supervised by a qualified occupational or physical therapist who makes an onsite supervisory visit at least once every 30 days. We note that the Medicare Benefit Policy Manual, Pub. 100–02, chapter 8, section 30.2.1 defines skilled nursing and/or skilled rehabilitation services as those services, furnished pursuant to physician orders, that, among other requirements, ''must be provided directly by or under the general supervision of these skilled nursing or skilled rehabilitation personnel to assure the safety of the patient and to achieve the medically desired result.'' The same manual provision notes that in the SNF setting, skilled nursing or skilled rehabilitation personnel include PTs, OTs, and SLPs. However, since 2005 in the private practice setting, we have required direct supervision for physical and occupational therapy services furnished by PTAs and OTAs, requiring an OTPP or PTPP to be immediately available to furnish assistance and direction throughout the performance of the procedure(s). We finalized this direct supervision policy in the CY 2005 PFS final rule (69 FR 66354 through 66356)—changing it from personal supervision, which required the OTPP or PTPP to be in the same room as the therapy assistant when they were providing the therapy services. Under the current regulations §§ 410.59(c)(2) and 410.60(c)(2), all services not performed personally by the OTPP or PTPP, respectively, must be performed under the direct supervision of the therapist by employees of the practice. Subsequently, in the CY 2008 PFS final rule (72 FR 66328 through 66332), we updated the qualification standards at 42 CFR part 484 for OTs, OTAs, PTs, PTAs, along with those for speech-language pathologists (SLPs).

Over the last several years, interested parties have requested that we revise our direct supervision policy for PTPPs and OTPPs to align with the general supervision policy for physical and occupational therapists working in Medicare institutional providers that provide therapy services (for example, outpatient hospitals, rehabilitation agencies, SNFs and CORFs), to allow for the general supervision of their therapy assistants. Additionally, the interested parties have informed us that all-but-one State allows for general supervision of OTAs and at least 44 States allow for the general supervision of PTAs, via their respective State laws and policies.

We are considering whether to revise the current direct supervision policy for PTPPs and OTPPs of their PTAs and OTAs, to general supervision for all physical therapy and occupational therapy services furnished in these private practices at this time, and are soliciting comments from the public that we may consider for possible future rulemaking. We are particularly interested in receiving comments regarding the possibility of changing the PTA and OTA supervision policy from direct supervision to general supervision in the private practice setting, and whether a general supervision policy could have implications for situations or conditions raised below:

- Because we want to ensure quality of care for therapy patients, could the general supervision policy raise safety concerns for therapy patients if the PT or OT is not immediately available to assist if needed? Do State laws and policies allow a PTA or OTA to practice without a therapist in a therapy office or in a patient's home?
- Could any safety concerns be addressed by limiting the types of services permitted under a general supervision policy?
- Would a general supervision policy be enhanced with a periodic visit by the PT or OT to provide services to the patient? If so, what number of visits or time period should we consider?
- Would a general supervision policy potentially cause a change in utilization? Would such a change in the supervision policy cause a difference in hiring actions by the PT or OT with respect to therapy assistants?

Interested parties have been requesting that CMS reconsider its supervision policies with respect to occupational therapy or physical therapy services, and in light of experiences during the PHE for COVID–19, we may consider proposing a general supervision policy for all services furnished by OTAs and PTAs employed by a PTPP or OTPP in the future after reviewing the comments and supporting data in response to this comment solicitation. We are, therefore, soliciting public comment, along with supporting data, about the questions and concerns we highlighted above, for our consideration for possible future rulemaking. We are further interested in public comment regarding changing §§ 410.59(a)(3)(ii), 410.59(c)(2), 410.60(a)(3)(ii), and 410.60(c)(2) to allow for general supervision of OTAs and PTAs by the OTPP and PTPP, respectively, when furnishing therapy services. Additionally, we are seeking public comment for our consideration for possible future rulemaking regarding any appropriate exceptions to allowing general supervision in the furnishing of therapy services.

2. KX Modifier Thresholds

Formerly referred to as the therapy cap amounts, the KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, February 9, 2018). These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the percentage increase in the Medicare Economic Index (MEI). In the CY 2023 PFS final rule (87 FR 69688 through 69710), we rebased and revised the MEI to a 2017 base year. Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2024, we propose to increase the CY 2023 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be

4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through the fourth quarter of 2022.[31] Multiplying the CY 2023 KX modifier threshold amount of $2,230 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent ($2,230 × 1.045), and rounding to the nearest $10.00, results in a proposed CY 2024 KX modifier threshold amount of $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2024 2017-based MEI percentage increase) later this year, we would use such data, if appropriate, to determine the CY 2024 MEI percentage increase and would apply that new estimate to formulate our values in the CY 2024 PFS final rule.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 until CY 2028, when it will be updated by the percentage increase in the MEI. Consequently, for CY 2024, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

(1) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(2) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(3) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(4) The services are furnished to treat a type of medical condition.

(5) The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable MPPR amount for services of CMS-designated ''always therapy'' services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceeds one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Through the use of the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied. (See the CY 2023 PFS final rule at 87 FR 69650 through 69651.)

3. Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals

During the CY 2022 PFS rulemaking, we adopted a regulation at § 410.72(d) that requires the services that RDs and nutrition professionals furnish to beneficiaries to be directly performed by them. This is based on the MNT regulations at subpart G, §§ 410.130–410.134. When developing this policy, we were only referring to MNT services. These MNT services are distinct from the DSMT services that RDs or nutrition professionals may furnish when they are or represent an accredited DSMT entity.

We note that the RD or nutrition professional, when named in or a sponsor of an accredited DSMT entity, may act as the DSMT certified provider, which is defined at section 1861(qq) of the Act as a physician, or other individual or entity to which Medicare makes payment for other services. RDs and nutrition professionals may qualify as DSMT certified providers within the meaning of the statute since they provide and bill for MNT services. This is reinforced in our sub-regulatory manual provisions (Pub. 100–02, Chapter 15, section 300.2), which specifies that DSMT certified providers may bill and be paid for the entire DSMT program and further clarifies that the RD or nutrition professional is eligible to bill on behalf of an entire DSMT program (or entity) on or after January 1, 2002, after obtaining a Medicare provider number. In addition, section 1861(qq) of the Act requires that DSMT certified providers meet quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board. DSMT entities are required to meet the National Standards for Diabetes Self-management Education Programs (NSDSMEP) set of quality standards at § 410.144(b). DSMT entities are also required to be recognized or accredited by CMS Accreditation Organizations (AOs). There are currently two national DSMT AOs—the American Diabetes Association (ADA) or the Association of Diabetes Care & Education Specialists (ADCES) (Medicare Program Integrity Manual, Pub. 100–08, chapter 10, section 10.2.4.B). The ADA and ADCES also review and approve the credentials of DSMT program instructors.

Interested parties have alerted us that the wording of § 410.72(d) has caused confusion for DSMT entities/suppliers and Part B Medicare Administrative Contractors (MACs) about whether RD or nutrition professionals must personally provide DSMT services. To alleviate any confusion, we believe a clarification is needed to distinguish between when a RD or nutritional professional is personally providing MNT services, in accordance with the MNT regulations, and when they are acting as or on behalf of an accredited DSMT entity and billing for DSMT services that may be provided by a group of other professionals working under an accredited DSMT entity, for example registered nurses (RNs), pharmacists, or RDs other than the sponsoring RD. Under the NSDSMEP quality standards, the RD, RN, or pharmacist is permitted to provide the educational DSMT services on a solo basis, that is without a multi-disciplinary team; however, only the RD or nutrition professional, when enrolled as a Medicare supplier, in these accredited DSMT entities is authorized by statute at section 1861(qq)(2)(A) to bill Medicare on behalf of the entire DSMT entity as the DSMT certified provider.

[31] IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the MEI and other CMS market baskets.

Consequently, we propose to amend the regulation at § 410.72(d) to clarify that a RD or nutrition professional must personally perform MNT services. Additionally, we propose to clarify that a RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services. We propose to clarify § 410.72(d) to provide that, except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

4. DSMT Telehealth Issues

(a) Distant Site Practitioners

Since 2006, RDs and nutrition professionals have been recognized as distant site practitioners for purposes of Medicare telehealth services under section 1834(m)(4)(E) of the Act. Section 1834(m)(4)(E) of the Act specifies that the practitioners listed at section 1842(b)(18)(C) of the Act, which include RDs and nutrition professionals as of 2006, can serve as distant site practitioners for Medicare telehealth services. Our regulations and sub-regulatory policies for Medicare telehealth services do not address scenarios involving the furnishing of DSMT services via telehealth when the actual services are personally furnished by individuals who provide them, for example, RNs, pharmacists, or other multidisciplinary team members, who are not recognized as telehealth distant site practitioners under the statutory definition. In keeping with the NSDSMEP quality standards, an RD is often part of a DSMT entity, and when they are, they can be considered a ''certified provider'' when they are enrolled in Medicare and intend to bill for the DSMT services, in accordance with the statutory provision at section 1861(qq)(2)(A) of the Act, which defines certified providers as physicians, or other individuals or entities designated by the Secretary, that, in addition to providing DSMT services, provides other items or services for which Medicare payment may be made. As we noted previously in this section of the proposed rule, there may be other RDs among the group or team of professionals, along with RNs and/or pharmacists, that are performing DSMT services in addition to the sponsoring or billing RD or nutrition professional functioning as the certified provider. Additionally, our Medicare Benefit Policy Manual, Pub. 100–02, Chapter 15, section 300.2 clarifies that these certified providers, including RDs or nutrition professionals, may bill for services of the DSMT entity. Since we allow RDs and other DSMT certified providers to bill on behalf of the DSMT entity when other professionals personally furnish the service in face-to-face encounters, we believe that this should also be our policy when DSMT is furnished as a Medicare telehealth service. To increase access to DSMT telehealth services, we are proposing to codify billing rules for DSMT services furnished as Medicare telehealth services at § 410.78(b)(2)(x) to allow distant site practitioners who can appropriately report DSMT services furnished in person by the DSMT entity, such as RDs and nutrition professionals, physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs), to also report DSMT services furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity. This proposed revision to our regulation will preserve access to DSMT services via telehealth for Medicare beneficiaries in cases where the DSMT service is provided in accordance with the NSDSMEP quality standards. We note that DSMT services are on the Medicare Telehealth Services List, and are subject to the requirements and conditions of payment under section 1834(m) of the Act and § 410.78 of our regulations, including originating site and geographic location requirements, when they are in effect. See section II.D. for a discussion of Medicare telehealth policies.

(b) Telehealth Injection Training for Insulin-Dependent Beneficiaries

Currently, our manual instruction for Payment for Diabetes Self-Management Training (DSMT) in the Medicare Claims Processing Manual, Pub. 100–04, chapter 12, section 190.3.6, requires 1 hour of the 10-hour DSMT benefit's initial training and 1 hour of the 2-hour follow-up annual training to be furnished in-person to allow for effective injection training when injection training is applicable for insulin-dependent beneficiaries. This policy was clarified for 2019 to specify that in-person training only applies to a beneficiary for whom the injection training was applicable via CMS Transmittal 4173, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4173CP.pdf*.

We believe that, with the expansion of the use of telehealth during the PHE for COVID–19, there have been significant changes in clinical standards, guidelines, and best practices regarding services furnished using interactive telecommunications technology, including for injection training for insulin-dependent patients. We do not want our policies to prevent injection training via telehealth when clinically appropriate. Consequently, we are proposing to revise our policy at 410.78(e) to allow the 1 hour of in-person training (for initial and/or follow-up training), when required for insulin-dependent beneficiaries, to be provided via telehealth. If finalized, we anticipate revising the Medicare Claims Processing Manual, Pub. 100–04, chapter 12, section 190.3.6 to reflect that flexibility.

J. Advancing Access to Behavioral Health Services

1. Implementation of Section 4121(a) of the Consolidated Appropriations Act, 2023

a. Statutory Amendments

Section 4121(a) of Division FF, Title IV, Subtitle C of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022), Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program, provides for Medicare coverage of and payment for the services of health care professionals who meet the qualifications for marriage and family therapists (MFTs) and mental health counselors (MHCs) when billed by these professionals.

Specifically, section 4121(a)(1) of the CAA, 2023 amended section 1861(s)(2) of the Act by adding a new benefit category under Medicare Part B in new subparagraph (II) to include marriage and family therapist services (as defined in an added section 1861(lll)(1) of the Act) and mental health counselor services (as defined in an added section 1861(lll)(3) of the Act).

Section 4121(a)(2) of the CAA, 2023 added a new subsection (lll) to section 1861 of the Act, which defines marriage and family therapist services, marriage and family therapist (MFT), mental health counselor services, and mental health counselor (MHC). Section 1861(lll)(1) of the Act defines ''marriage and family therapist services'' as services furnished by an MFT for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or

as an incident to a physician's professional service. Section 1861(lll)(2) of the Act defines the term MFT to mean an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to State law of the State in which such individual furnishes marriage and family therapist services;
- Is licensed or certified as a MFT by the State in which such individual furnishes such services;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and
- Meets such other requirements as specified by the Secretary.

Section 1861(lll)(3) of the Act defines ''mental health counselor services'' as services furnished by a mental health counselor (MHC) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MHC is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service. Section 1861(lll)(4) of the Act defining MHC as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under State law of the State in which such individual furnishes MHC services;
- Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are furnished;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in mental health counseling; and
- Meets such other requirements as specified by the Secretary.

Section 4121(a)(3) of the CAA, 2023 amended section 1833(a)(1) of the Act to add a new subparagraph (FF), which provides that, with respect to MFT services and MHC services under section 1861(s)(2)(II) of the Act, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L).

Section 1888(e)(2)(A)(ii) of the Act, as amended by section 4121(a)(4) of the CAA, 2023, excludes MFT and MHC services from consolidated billing requirements under the skilled nursing facility (SNF) prospective payment system. For further discussion about this exclusion of MFT and MHC services from SNF consolidated billing, see discussion in the FY 2024 SNF Prospective Payment System (PPS) proposed rule (88 FR 21316).[32] Section 4121(a)(5) of the CAA, 2023 amended section 1842(b)(18)(C) of the Act to add MFTs and MHCs to the list of practitioners whose services can only be paid by Medicare on an assignment-related basis. MFTs, MHCs, and other practitioners described in section 1842(b)(18)(C) of the Act may not bill (or collect any amount from) the beneficiary or another person for any services for which Medicare makes payment, except for deductible and coinsurance amounts applicable under Part B. More information on assignment of claims can be found at in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 1, Section 30.3.1.

We also note that section 1861(aa)(1)(B) of the Act was amended by section 4121(b)(1) of the CAA, 2023 to add services furnished by MFTs and MHCs to the definition of rural health clinic services. See section III.B of this proposed rule for discussion related to MFT and MHC services furnished in RHCs and FQHCs.

Additionally, section 1861(dd)(2)(B)(i)(III) of the Act was amended by 4121(b)(2) of the CAA, 2023 to require a hospice program to have an interdisciplinary team that includes at least one social worker, MFT or MHC. For further discussion about this amended requirement for hospice program interdisciplinary teams, see section III.O of this proposed rule.

b. Proposed Changes to Regulations

Consistent with the changes to the statute described above, we are proposing to create two new regulation sections at § 410.53 and § 410.54 to codify the coverage provisions for MFTs and MHCs, respectively.

Specifically, we are proposing to define a marriage and family therapist at § 410.53 as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;
- After obtaining such degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and
- Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

We note that we are aware that there may be some States that require a number of hours of clinical supervised experience for MFT licensure that may be inconsistent with the statutory requirement in section 1861(s)(2) of the Act that requires at least 2 years of clinical supervised experience. We believe it could be possible for an MFT to have completed the required number of clinical supervised hours required for licensure in their State, but to have accomplished this in less than two years. Therefore, we are proposing a requirement for MFTs to have performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience, if consistent with State licensure requirements. We believe that 3,000 hours is roughly equivalent to the statutory requirement to have performed 2 years of clinical supervised experience and note that the regulatory requirements for clinical social workers (CSWs) at § 410.73(a)(3)(ii) allow 2 years or 3,000 hours of supervised experience. Additionally, the statutory benefit category for both MFTs and CSWs is defined as services for the diagnosis and treatment of mental illnesses. As such, we believe it would be appropriate to provide similar flexibility in the required amount of clinical supervised experience for MFTs and CSWs. We are also interested in public comments regarding States that have a supervised clinical hour requirement for MFT licensure that is less than 2 years.

We are proposing to define ''Marriage and family therapist services'' at § 410.53(b)(1) as services furnished by a marriage and family therapist for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. We are also proposing at § 410.53(b)(1) that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

Lastly, we are proposing at § 410.53(b)(2) that the following services do not fall under the Medicare Part B benefit category for MFT services:

[32] *https://www.govinfo.gov/content/pkg/FR-2023-04-10/pdf/2023-07137.pdf.*

• Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

Similarly, we are proposing to define a mental health counselor at § 410.54 as an individual who:

• Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;

• After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

• Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are performed. As previously explained for MFTs, and for the same reasons, we are proposing a requirement for MHCs to have performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience, if consistent with State licensure requirements. We believe that 3,000 hours is roughly equivalent to the statutory requirement to have performed 2 years of clinical supervised experience and note that the regulatory requirements for clinical social workers at § 410.73(a)(3)(ii) allows 2 years or 3,000 hours. The MHC statutory benefit category authorizes MHCs to furnish services for the diagnosis and treatment of mental illnesses as it does for CSWs. We are also interested in public comments regarding States that have a supervised clinical hour requirement for MHC licensure that is less than 2 years.

We are proposing to define ''mental health counselor services'' at § 410.54(b)(1) as services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. We are also proposing at § 410.54(b)(1) that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service.

We are proposing at § 410.54(b)(2) that the following services do not fall under the Medicare Part B benefit category for MHC services:

• Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

We are proposing to amend § 410.10 to add marriage and family therapist services and mental health counselor services to the list of included medical and other health services. We are also proposing to amend § 410.150 to add marriage and family therapists and mental health counselors, to the list of individuals or entities to whom payment is made.

Currently, § 410.32(a)(2) lists the health care practitioners that may order diagnostic tests. Since this list currently includes CSWs and clinical psychologists (CPs), who are also authorized by statute to furnish services for the diagnosis and treatment of mental illnesses, we are proposing to amend § 410.32(a)(2) to add MFTs and MHCs to the list of practitioners who may order diagnostic tests, as for the other non-physician practitioners, to the extent that the MFT or MHC is legally authorized to perform the service under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished.

We are also proposing to codify in a new § 414.53 the payment amounts authorized under section 1833(a)(1)(FF) for MFT and MHC services. Additionally, we are proposing to codify at § 414.53 the payment amount for clinical social worker (CSW) services as authorized under section 1833(a)(1)(F) of the Act. As we reviewed our regulations to implement section 4121 of the CAA, 2023, we found that the payment amounts for CSWs are not yet codified under regulations. Specifically, we are proposing to add that the payment amount for CSW, MFT, and MHC services is 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for clinical psychologist services under the PFS.

We are also proposing to add MFTs and MHCs to the list of practitioners who are eligible to furnish Medicare telehealth services at the distant site. See section II.D. of this proposed rule for a discussion of this proposal.

Additionally, we are proposing to allow Addiction Counselors who meet all of the applicable requirements (possess a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor; after obtaining such degree have performed at least 2 years (or, as proposed, 3,000 hours) of clinical supervised experience in mental health counseling; and licensed or certified as a MHC, clinical professional counselor, or professional counselor by the State in which the services are furnished) to enroll in Medicare as MHCs. That is, under this proposal, Addiction Counselors would be considered Mental Health Counselors and would be eligible to enroll and bill Medicare for MHC services if they meet these requirements. We understand there is variation in the terminology used for licensure across States for MHCs and MFTs and are seeking information pertaining to other types of professionals who may meet the applicable requirements for enrollment as mental health counselors. We note that in past rulemaking, we have discussed the term 'mental health' to be inclusive of diagnosis and treatment of substance use disorders. For example, in the CY 2022 PFS final rule (86 FR 65061), we stated that SUD services are considered mental health services for the purposes of the expanded definition of ''interactive telecommunications system.'' We propose to apply that same interpretation for purposes of the mental health services included in the definition of MFT, MHC, and to clarify that the same interpretation applies for CSW, and CP services.

c. Coding Updates To Allow MFT and MHC Billing

In light of the new statutory benefits for MFTs and MHCs authorized by section 4121(a) of the CAA, 2023, we have considered whether updates to certain HCPCS codes are required in order to allow MFTs and MHCs to bill for the services described by those HCPCS codes. In the CY 2023 PFS final rule, we finalized new coding and payment for General Behavioral Health Integration services performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW serve as the focal point of care integration. In light of the new coverage under Medicare for MFT and MHC services for the diagnosis and treatment of mental illness, we are proposing to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service. We note that MFTs and MHCs, like CSWs, are authorized by statute for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT or MHC is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or

as an incident to a physician's professional service. The proposed code descriptor for HCPCS code G0323 is: *Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist, clinical social worker, mental health counselor, or marriage and family therapist time, per calendar month. (These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)*

Lastly, we note that consistent with the proposed changes to valuation of CPT code 99484 in the Valuation of Specific Codes section (section II.E. of this proposed rule), which describes General BHI and is the crosswalk code used for valuation of HCPCS code G0323, we are also proposing conforming updates to the valuation for work and PE inputs for HCPCS code G0323. See section II.E. of this proposed rule for further discussion of changes to the valuation for HCPCS code G0323.

We welcome comments regarding any other HCPCS codes that may require updating to allow MFTs and MHCs to bill for the services described in the HCPCS code descriptor.

d. Medicare Enrollment of MFTs and MHCs

MFTs and MHCs who meet the applicable requirements (possess a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor; after obtaining such degree have performed at least 2 years (or, as proposed, 3,000 hours) of clinical supervised experience in mental health counseling; and is licensed or certified as a MHC, clinical professional counselor, or professional counselor by the State in which the services are furnished) described in detail above in this section, as finalized, will need to enroll in Medicare as MFTs and MHCs in order to submit claims for marriage and family therapist services and mental health counselor services, respectively, furnished to Medicare beneficiaries. Under § 424.510, a provider or supplier must complete, sign, and submit to its assigned MAC the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532; 104 Provider Enrollment, Chain, and Ownership System), captures information about the provider or supplier that is needed for CMS or its MACs to determine whether the provider or supplier meets all Medicare requirements. We propose that the MFT and MHC supplier types, like most non-physician practitioner types, be subject to limited-risk screening under § 424.518, for we have no basis on which to assign these suppliers as a class to a higher screening category.

MFTs and MHCs that meet the proposed requirements in §§ 410.53 and 410.54 as finalized, would enroll in Medicare via the Form CMS–855I application (Medicare Enrollment Application—Physicians and Non-Physician Practitioners; OMB No. 0938–1355) and could begin submitting their enrollment applications after the publication of the CY 2024 PFS final rule. However, as the new benefit categories authorized by section 4121(a) of the CAA, 2023, do not take effect until January 1, 2024, MFT or MHC claims for MFT or MHC services furnished to Medicare beneficiaries with dates of service prior to January 1, 2024 will not be payable under Medicare Part B. MFTs and MHCs can visit *https://www.cms.gov/medicare/provider-enrollment-and-certification* for basic information on the provider enrollment process.

2. Implementation of Section 4123 of the CAA, 2023

Section 4123(a)(1) of the CAA, 2023, Improving Mobile Crisis Care in Medicare, amended section 1848 of the Act by adding a new paragraph (b)(12) regarding payment for psychotherapy for crisis services furnished in an applicable site of service. New subparagraph (A) of section 1848(b)(12) of the Act requires the Secretary to establish new HCPCS codes under the PFS for services described in subparagraph (B) that are furnished on or after January 1, 2024. Subparagraph (B) of section 1848(b)(12) of the Act describes these services as psychotherapy for crisis services that are furnished in an applicable site of service. Section 1848(b)(12)(C) of the Act specifies that the payment amount for these psychotherapy for crisis services shall be equal to 150 percent of the fee schedule amount for non-facility sites of service for each year for the services identified (as of January 1, 2022) by HCPCS codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), and any succeeding codes.

For purposes of this provision, subparagraph (D)(i) of new section 1848(b)(12) of the Act defines an applicable site of service as a site of service other than a site where the facility rate under the PFS applies and other than an office setting, while subparagraph (D)(ii) requires that the code descriptors for these new psychotherapy for crisis services be the same as the services identified (as of January 1, 2022) by HCPCS codes 90838 and 90840, and any succeeding codes, except that the new codes shall be limited to services furnished in an applicable site of service.

Therefore, consistent with the requirements described in new paragraph (12) of section 1848(b) of the Act, we are proposing to create two new G-codes describing psychotherapy for crisis services furnished in any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting: HCPCS codes GPFC1 and GPFC2.

To identify the places of service that are assigned the non-facility rate, § 414.22(b)(5)(i) states that there are usually two levels of PE RVUs that correspond to each code paid under the PFS: facility PE RVUs and non-facility PE RVUs. Under § 414.22(b)(5)(i)(A), the facility PE RVUs apply to services furnished in a hospital, skilled nursing facility, community mental health center, hospice, ambulatory surgical center, or wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5), or for services furnished via telehealth under § 410.78 (though we note that special rules relating to the PHE for COVID–19 currently apply, and we include proposals regarding the place of service for telehealth services in section II.D). Under § 414.22(b)(5)(i)(B), the non-facility rate is paid in all other settings, including a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility. We provide the full list of places of service that are assigned a non-facility rate on the CMS website at *https://www.cms.gov/Medicare/Coding/place-of-service-codes.* We propose that the two new G-codes describing psychotherapy for crisis services can be

billed when the services are furnished in any non-facility place of service other than the physician's office setting. We also note that in the CY 2022 PFS final rule (86 FR 65059), in our discussion of Medicare telehealth services where the patient's home is a permissible originating site for services furnished for diagnosis, evaluation, or treatment of a mental health disorder, we indicated that we define the term ''home'' broadly to include temporary lodging, such as hotels and homeless shelters (86 FR 65059). We clarified that, for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, that would qualify as the patient's home. For purposes of implementing section 1848(b)(12) of the Act, we are proposing to use the same broad definition of the patient's home for purposes of these proposed G-codes describing psychotherapy for crisis services.

The proposed new G-codes and their descriptors are:

- GPFC1 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); first 60 minutes*); and
- GPFC2 (*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); each additional 30 minutes (List separately in addition to code for primary service)*).

As required by section 1848(b)(12)(C) of the Act, we are proposing to establish a fee schedule amount for these two new G-codes that is 150 percent of the current PFS non-facility RVUs for CPT codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*), respectively. Specifically, we are proposing to calculate the work, PE, and MP RVUs for HCPCS codes GPFC1 and GPFC2 by multiplying the work, PE, and MP RVUs for CPT codes 90839 and 90840, respectively, by 1.5.

We note that section 4123(a)(2) of the CAA, 2023 amends section 1848(c)(2)(B)(iv) of the Act to include a waiver of budget neutrality providing that subsection (b)(12) shall not be taken into account in applying PFS budget neutrality requirements under section 1848(c)(2)(B)(ii)(II) of the Act for 2024. Accordingly, we are proposing to exclude expected expenditures for HCPCS codes GPFC1 and GPFC2 from the budget neutrality calculation for CY 2024 PFS ratesetting.

Additionally, section 4123(d) of the CAA, 2023 requires that the Secretary use existing communication mechanisms to provide education and outreach to providers of services, physicians, and practitioners with respect to the ability of auxiliary personnel, including peer support specialists, to participate, consistent with applicable requirements for auxiliary personnel, in the furnishing of psychotherapy for crisis services billed under the PFS under section 1848 of the Act, behavioral health integration services, as well as other services that can be furnished to a Medicare beneficiary experiencing a mental or behavioral crisis. We understand that there are varying definitions of the term ''peer support specialist.'' The Substance Abuse and Mental Health Services Administration (SAMHSA) defines a ''peer support specialist'' as a person who uses their lived experience of recovery from mental illness and/or addiction, plus skills learned in formal training, to deliver services to promote recovery and resiliency. The essential principles of peer support include shared personal experience and empathy, a focus on individual strengths, and supporting individuals as they work toward recovery pursuant to a person-centered plan of care. However, for Medicare payment purposes, we note that the term auxiliary personnel is defined at § 410.26(a)(1) as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid, and all other Federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. We do not include definitions of any specific types of personnel who could be included under the definition of auxiliary personnel in our regulations and are not proposing to do so through this rule. CMS anticipates conducting this outreach and education through existing communications mechanisms as required by the CAA, 2023.

3. Implementation of Section 4124 of the Consolidated Appropriations Act, 2023 (CAA, 2023)

Section 4124 of the CAA, 2023, Ensuring Adequate Coverage of Outpatient Mental Health Services under the Medicare Program, establishes Medicare coverage and payment for intensive outpatient services for individuals with mental health needs when furnished by hospital outpatient departments, community mental health centers, RHCs, and FQHCs, effective January 1, 2024. Please see the discussion of our proposed implementation of section 4124 in the CY 2024 Outpatient Prospective Payment System (OPPS) proposed rule, section VIII. Payment for Partial Hospitalization and Intensive Outpatient Services.

4. Health Behavior Assessment and Intervention (HBAI) Services

The current Health and Behavior Assessment and Intervention codes (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, 96168, 96170, and 96171) were created by the CPT Editorial Panel during its September 2018 meeting. The CPT Editorial Panel deleted the six previous HBAI CPT codes and replaced them with nine new CPT codes. As discussed in the CY 2023 PFS final rule (87 FR 69541), the HBAI range of CPT codes are intended to be used for psychological assessment and treatment, when the primary diagnosis is a medical condition. A health behavior assessment under these HBAI services is conducted through health-focused clinical interviews, behavioral observation and clinical decision-making and includes evaluation of the person's responses to disease, illness or injury, outlook, coping strategies, motivation, and adherence to medical treatment. HBAI services are provided individually, to a group (two or more patients), and/or to the family, with or without the patient present, and include promotion of functional improvement, minimization of psychological and/or psychosocial barriers to recovery, and management of and improved coping with medical conditions. The HBAI codes apply to services that address psychological, behavioral, emotional, cognitive, and interpersonal factors in the treatment/management of people diagnosed with physical health issues. According to the CPT prefatory language in the CPT 2023 Professional Edition, the patient's primary diagnosis is physical in nature and the focus of the assessment and intervention is on factors complicating medical conditions and treatments. The HBAI codes capture services related to

physical health, such as adherence to medical treatment, symptom management, health-promoting behaviors, health related risky behaviors, and adjustment to physical illness.

In light of the new benefit categories authorized by section 4121(a)(2) of the CAA, 2023, which authorize MFTs and MHCs to furnish services for the diagnosis and treatment of mental illness, this prompted us to consider whether MFTs and MHCs could furnish and bill for HBAI services. Additionally, we re-examined whether CSWs could furnish and bill these HBAI codes given that their statutory benefit category also authorizes them to furnish services for the diagnosis and treatment of mental illnesses. We note that prior to the passage of the CAA, 2023, which authorized benefit categories for MFTs and MHCs, there was previously a National Coverage Determination (NCD) that stated, the CPT codes 96156, 96158, 96159, 96164, 96165, 96167 and 96168 may be used only by a Clinical Psychologist (CP), (Specialty Code 68). However, we note that this NCD was retired on December 8, 2022.[33]

Like CPs, who can currently bill Medicare for HBAI services, CSWs, MFTs, and MHCs have the education and training to address psychosocial barriers to meet the needs of patients with physical health conditions. In accordance with State law and scope of practice, CSWs, MFTs, and MHCs can assess, diagnose, and treat psychological and/or psychosocial behaviors associated with physical health conditions. Interested parties have informed us that like CSWs, MHCs and MFTs can play a key role in a multidisciplinary team approach that leads to successful outcomes in patient care, including offering integrated care within hospitals and medical practices where patients are diagnosed with physical health conditions. For example, mental health professionals such as MHCs and MFTs facilitate ''behavioral management and reinforcement, guided problem-solving, supporting patients in setting realistic and attainable goals, and teaching relaxation strategies for managing diabetes-related stressors.'' [34] In this role, mental health professionals such as CSWS, MHCs, and MFTs help patients manage mental health symptoms associated with a physical health condition. Moreover, according to the National Cancer Institute at the National Institutes of Health, mental health professionals can also provide emotional and social support to assist cancer patients in reducing ''levels of depression, anxiety, and disease and treatment-related symptoms among patients.'' [35] Therefore, we are proposing to allow the HBAI services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, to be billed by CSWs, MFTs, and MHCs, in addition to CPs. We note that in order for payment to be made under Medicare for HBAI services furnished to a beneficiary, the HBAI services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, in accordance with section 1862(a)(1)(A) of the Act.

5. Adjustments to Payment for Timed Behavioral Health Services

There is an ongoing behavioral health crisis in the United States, which has been exacerbated by the COVID–19 pandemic, the overdose crisis,[36] and worsening behavioral healthcare workforce shortages.[37] Public comments received in response to the CY 2023 PFS proposed rule described practices that furnish treatment for behavioral health conditions experiencing difficulty recruiting and retaining behavioral health clinicians and expressed concern that people are experiencing unprecedented delays in receiving medically necessary services across care settings. Commenters described workforce shortages nationwide that, combined with increasing demand for behavioral health care services, have limited Medicare beneficiary access to these vital services. Prior to the pandemic, the Health Resources and Services Administration (HRSA) projected shortages of seven selected types of behavioral health providers by 2025.[38] As of March 31, 2023, HRSA designated more than 6,635 health professional shortage areas for mental health, with more than one-third of Americans living in these shortage designations.[39] Additionally, according to SAMHSA's guide on *Addressing Burnout in the Behavioral Health Workforce Through Organizational Strategies,* staffing shortages, and high turnover rates place enormous demands on the workforce, jeopardizing the provision of care, especially to underserved individuals.[40] The behavioral health workforce experiences high levels of work-related stress, relatively low salaries, and full caseloads; these combined factors place individuals working in the behavioral health field at high risk for experiencing burnout.[41] Over 50 percent of behavioral health providers report experiencing burnout symptoms. The rate of burnout will likely increase, given the continued growth in the number of people seeking behavioral health care, behavioral health staffing, and retention challenges.[42]

In CY 2023 PFS rulemaking, we sought comment on how we can best help ensure beneficiary access to behavioral health services, including any potential adjustments to the PFS ratesetting methodology, for example, any adjustments to systematically address the impact on behavioral health services paid under the PFS. We described that as part of our review of our payment policies and systems, we understand that the PFS ratesetting methodology and application of budget neutrality may impact certain services more significantly than others based on factors such as how frequently codes are revalued and the ratio of physician work to PE. In the CY 2018 PFS final rule (82 FR 52999), we discussed feedback we received from some interested parties suggesting that, for codes with very low direct PE inputs, our methodology for allocating indirect PE does not produce a differential between facility and nonfacility PE RVUs that accurately reflects the relative indirect costs involved in furnishing services in non-facility settings. We stated that primary therapy and counseling services available to Medicare beneficiaries for the treatment of behavioral health conditions, including substance use disorders, are among the services most

[33] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57754&ver=12&=.*

[34] Powell PW, Hilliard ME, Anderson BJ (2014). Motivational interviewing to promote adherence behaviors in pediatric type 1 diabetes. *Curr Diab Rep.* 2014;14(10):531. 10.1007/sll892–014–0531–z.

[35] National Cancer Institute at the National Institutes of Health, (nd). ''Stress and Cancer'' *https://www.cancer.gov/about-cancer/coping/feelings/stress-fact-sheet.*

[36] *https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/.*

[37] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[38] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[39] Health Resources and Services Administration, Health Workforce Shortage Areas, *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[40] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/bh-workforce-projections-fact-sheet.pdf.*

[41] Kelly, R.J., Hearld, L.R. Burnout and Leadership Style in Behavioral Health Care: a Literature Review. *J Behav Health Serv Res* 47, 581–600 (2020). *https://doi.org/10.1007/s11414-019-09679-z.*

[42] *https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep22-06-02-005.pdf.*

affected by our methodology. For example, we stated at the time that, for the most commonly reported psychotherapy service (CPT code 90834), the difference between the nonfacility and facility PE RVUs was only 0.02 RVUs, which seemed unlikely to represent the difference in relative PE resource costs in terms of administrative labor, office expense, and all other expenses incurred by the billing practitioner for 45 minutes of psychotherapy services when furnished in the office setting versus the facility setting. We agreed with these interested parties that the site of service differential for these services produced by our PE methodology seems unlikely to reflect the relative resource costs for the practitioners furnishing these services in nonfacility settings. For example, we believe the 0.02 RVUs, which translated at the time to approximately $0.72, was unlikely to reflect the relative administrative labor, office rent, and other overhead involved in furnishing the 45-minute psychotherapy service in a nonfacility setting. Consequently, we modified our PE methodology to establish a minimum nonfacility PE RVU for certain outlier codes with very low direct PE inputs as compared to work RVUs, most of which are primarily furnished by behavioral health professionals. We finalized a policy to implement only one quarter of the minimum value for nonfacility indirect PE for the identified outlier codes over a 4-year transition period, beginning with CY 2018. We stated that we recognized that this change in the PE methodology could significantly impact the allocation of indirect PE RVUs across all PFS services (82 FR 53000).

In light of increasing patient needs for behavioral health services and continued workforce shortages, we have been examining a number of dynamics in our processes for developing values for behavioral health services under the PFS. We continue to consider approaches to ensuring that the relative values we establish for these services accurately reflect the resources involved in furnishing them, especially since any potential systemic undervaluation could serve as an economic deterrent to furnishing these kinds of services and be a contributing factor to the workforce shortage.

Interested parties have long raised concerns regarding the valuation of services that primarily involve person-to-person interactions with beneficiaries, particularly those services that are comprised of conversational interactions rather than physical interactions, because these services require minimal equipment and supplies compared to other services, and therefore, valuation is based almost entirely on the practitioner's work. Because the physician/practitioner work RVU is developed based on the time and intensity of the service, the issues regarding the valuation of these types of services are particularly pronounced for services that are billed in time units (like psychotherapy codes) that directly reflect the practitioner time inputs used in developing work RVUs, compared to other services that are not billed in time units in which work RVUs are based on estimates of typical time, usually based on survey data. For example, a 2016 report by the Urban Institute entitled *Collecting Empirical Physician Time Data*[43] (the Urban Institute report) reviewed empirical time estimates for 60 services paid under the PFS with relative values developed based on time estimates derived from survey data (as opposed to actual reported time). The Urban Institute report suggested that there may be systemic overestimations of times for these services within the PFS, which would lead to overvaluation of these services and, by implication, undervaluation of other services.

The dynamic described by the Urban Institute report can lead to systemic undervaluation for some kinds of time-based codes for several, interrelated reasons. First, overestimates of time for some kinds of codes compared to other kinds of codes results in ''implied intensity'' (that is the ratio of work RVU/per minute, sometimes referred to by the AMA RUC as intra-service work per unit of time, or IWPUT) that is artificially low. This is important since we understand that the implied intensity is used as part of the AMA RUC review of survey data to contextualize the credibility of data and the resulting recommended work RVUs compared to codes with similar times. CMS' review of the RUC recommendations similarly utilizes implied intensity as important contextual information in order to assess the relative values assigned to particular services.

The second reason this dynamic could result in potential undervaluation of certain services is that time-based codes that describe one-on-one time with the patient are highly unlikely to become more efficient over multiple years. In contrast, surgical procedures tend to become more efficient over the years as they become more common, professionals gain more experience with them, improved technology is deployed, and other general operational improvements are implemented. Meanwhile, 45 minutes of psychotherapy remains static in terms of efficiency since, by definition, it requires 45 minutes of time, personally spent by the billing professional, one-on-one with the patient. Moreover, even if there were efficiencies that reduced the time required to furnish therapy services, the services would then be reported with time-based codes with lower total values. Additionally, in contrast to services such as procedures that utilize clinical staff, no part of the one-on-one therapy service can be performed by clinical staff working with the billing professional. This means that any overestimations in the initial estimates of time used to established work times and values, as discussed above, are likely compounded over time as there are gains in efficiencies for some services in terms of time, clinical staff delegation, and improved technology, but no such gains for other services.

For many professionals who provide a heterogenous range of services paid under the PFS, this phenomenon may not have a significant overall impact on their Medicare PFS payments. However, this phenomenon would have an outsized impact on Medicare PFS payments for professionals who predominantly furnish services involving person-to-person interactions with patients that are reported and valued in time-based units. It would not be logical to assume that the marketplace ignores this dynamic, since the opportunity for increased revenue generation through efficiency for timed, one-on-one services is limited as compared to services for which there are multiple avenues to gain efficiencies.

We also recognize that, while this underlying valuation dynamic may create distortion of increasing magnitude over time, the quickly changing needs of Medicare beneficiaries relative to behavioral health also likely contribute to systemic distortion. This is especially the case as beneficiaries rely on behavioral health professionals for ongoing care of chronic and acute mental health needs. In other words, at the same time that the intensity of the work involved in furnishing services to Medicare beneficiaries increases, the work RVUs assigned to these services may be initially undervalued relative to other services that are valued based on potentially inflated time data, and therefore, may not accurately reflect the current relative resource costs associated with these services.

[43] *https://www.urban.org/sites/default/files/publication/87771/2001123-collecting-empirical-physician-time-data-piloting-approach-for-validating-work-relative-value-units_0.pdf.*

One approach to curb the impact of this dynamic would be to conduct more frequent revaluations of these kinds of services, including timed psychotherapy services. However, our current valuation process relies primarily, as noted, on times reported through survey data of professionals who furnish these services and assessment by the RUC of those survey data. We believe that survey results from the professionals that currently provide behavioral health services, including physicians, psychologists, and social workers could reflect the increased intensity of the work due to changes in the complexity of care for beneficiaries, but would be unlikely to address any relative undervaluation of work estimates. We are interested in working with the broader community, including the AMA RUC, to address these specific concerns over the long term.

However, given the emerging need for access to behavioral health care and the continuing difficulties in behavioral health workforce capacity, we believe it would be appropriate to take immediate steps to improve the accuracy of the valuation of these services until we can develop systemic solutions to longstanding process limitations. Consequently, we propose to address the immediate need for improvement in valuation for timed psychotherapy services in such a way that considers the policy we initially finalized in the CY 2020 PFS final rule (84 FR 62856) to address valuation distortions for primary and longitudinal care through implementation of an add-on code for office/outpatient E/M services that involve inherent complexity, and are proposing to reestablish in this rule. Our proposed implementation of that policy is discussed in section II.F. of this proposed rule. Like E/M visits that are furnished for primary and longitudinal care, we believe that the psychotherapy codes similarly describe treatment that is ongoing or longitudinal, and therefore, we believe it is appropriate to propose to address the need for improvement in valuation for timed psychotherapy services based on the proposed valuation for the inherent complexity add-on code for office/outpatient E/M services.

Under this proposal, we would apply an adjustment to the work RVUs *for* the psychotherapy codes payable under the PFS. We propose to base this adjustment on the difference in total work RVUs for office/outpatient E/M visit codes (CPT codes 99202–99205 and 99211–99215) billed with the proposed inherent complexity add-on code (HCPCS code G2211) compared to the total work RVUs for visits that are not billed with the inherent complexity add-on code. This would result in an approximate upward adjustment of 19.1 percent for work RVUs for these services, comparable to the relative difference in office/outpatient visits that are also systemically undervalued absent such an adjustment, which we are proposing to implement over a 4-year transition. In making significant adjustments to RVUs in past rulemaking, we have implemented such changes using a 4-year transition, noting that a transition period allows for a more gradual adjustment for affected practitioners. We are proposing to apply this adjustment to the following time-based psychotherapy codes that describe one-on-one time with the patient that are significantly unlikely to become more efficient over multiple years: CPT code 90832 (*Psychotherapy, 30 minutes with patient*); CPT code 90834 (*Psychotherapy, 45 minutes with patient*); CPT code 90837 (*Psychotherapy, 60 minutes with patient*); 90839 (*Psychotherapy for crisis; first 60 minutes*); CPT code 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service*); CPT code 90845 (*Psychoanalysis*); 90846 (*Family psychotherapy (without the patient present), 50 minutes*); CPT code 90847 (*Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes*); CPT code 90849 (*Multiple-family group psychotherapy*); CPT code 90853 (*Group psychotherapy (other than of a multiple-family group*) and newly proposed HCPCS codes GPFC1 and GPFC2 ((*Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting*). We are not proposing to include CPT codes 90833, 90836, and 90838 in this list of codes for which we would make the adjustment because these are add-on codes for psychotherapy that is performed with an E/M visit and under our proposal described at section II.E of this proposed rule, E/M codes will be eligible to be billed with HCPCS code G2211, therefore, the psychotherapy codes that are performed with an E/M visit will already be eligible for an adjustment to account for the resources costs involved in furnishing longitudinal care. We believe that implementing an adjustment to the work RVUs for psychotherapy services concurrent with implementation of HCPCS code G2211 will help address distortions that may occur within our valuation process that may otherwise result in understated estimates of the relative resources involved in furnishing psychotherapy services. We recognize that many other services share some similarities with these psychotherapy services. For example, there are other services that are reported in time units. Likewise, there are other codes that primarily describe conversational interactions between medical professionals and beneficiaries. However, we believe that these services are unique because neither technology nor clinical staff can be utilized to increase efficiency, and because these services represent the significant majority of services furnished by certain types of professionals. If finalized, the implementation of this proposal for CY 2024, concurrent with the proposal to implement the inherent complexity add-on code, if finalized, will also mitigate any negative impact in valuation for psychotherapy services based on redistributive impacts if we were to finalize only the inherent complexity add-on code for E/M visits without proposing and finalizing any adjustments for psychotherapy. We welcome comments on this proposal, including and especially how the PFS valuation processes for these services and other services with similar characteristics can be improved in the future in order to mitigate the kinds of distortions described above.

Additionally, as noted above in this section, in the CY 2018 PFS final rule (82 FR 52999), we identified a set of outlier codes for which we believed it would be appropriate to establish a minimum nonfacility indirect PE RVU that would be a better reflection of the resources involved in furnishing these services. For each of the outlier codes, we compared the ratio between indirect PE RVUs and work RVUs that result from the application of the standard methodology to the ratio for a marker code, which was CPT code 99213. The finalized change in the methodology then increased the allocation of indirect PE RVUs to the outlier codes to at least one quarter of the difference between the two ratios. We stated we believed this approach reflected a reasonable minimum allocation of indirect PE RVUs, but that we did not have empirical data that would be useful in establishing a more precise number. We finalized implementation of one quarter of the minimum value for nonfacility indirect PE for the identified outlier codes. We stated that we recognized that this change in the PE methodology could have a significant impact on the allocation of indirect PE RVUs across all PFS services and finalized that we

would implement this change over a 4-year transition, beginning in CY 2018 and ending in CY 2021. We welcome comments on whether we should consider further adjustments to the nonfacility indirect PE for the identified outlier codes. Specifically, we request comment on whether this minimum value adjustment to the indirect PE for certain services sufficiently accounted for the resources involved in furnishing these services, or whether we should consider further adjustments, such as applying 50 percent of the calculated minimum value for nonfacility indirect PE values for these services, and whether we should consider implementing further changes using a similar 4-year transition.

6. Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) Bundle (HCPCS Codes G2086–G2088)

In the CY 2023 PFS final rule (87 FR 69772 through 69774), we finalized a modification to the payment rate for the non-drug component of the bundled payment for episodes of care under the Opioid Treatment Program (OTP) benefit to base the rate for individual therapy on a crosswalk to CPT code 90834 (*Psychotherapy, 45 minutes with patient*), which reflects a 45-minute psychotherapy session, instead of a crosswalk to CPT code 90832 (*Psychotherapy, 30 minutes with patient*), as was our current policy at the time. We received public comments urging us to consider adopting this modification for other bundled payments for SUD under the PFS, such as the bundled rate for office-based SUD treatment, to reflect the complexity of treating these patients and ensure that there is consistent and sufficient access to counseling for SUD across settings of treatment. The commenters noted that some patients who are prescribed buprenorphine in non-OTP settings will have similarly complex care needs requiring more intensive therapeutic care, and that by recognizing the appropriate complexity and intensity of the services in setting the rates, CMS can incentivize more office-based practices to offer these services and build out the treatment teams that deliver this care.

In the CY 2020 PFS final rule (84 FR 62673 through 62677), we finalized the establishment of bundled payments for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. We stated that for the purposes of valuation of HCPCS codes G2086 (*Office-based treatment for a substance use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month*) and G2087 (*Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month*), we assumed two individual psychotherapy sessions per month and four group psychotherapy sessions per month, and noted that we understand that the number of therapy and counseling sessions furnished per month will vary among patients and also fluctuate over time based on the individual patient's needs. We are persuaded by the public comments received in response to the CY 2023 PFS proposed rule requesting that these codes be priced consistent with the crosswalk codes used to value the bundled payments made for OUD treatment services furnished at OTPs, as beneficiaries receiving buprenorphine in settings outside of OTPs may have similarly complex care needs as compared to beneficiaries receiving OUD treatment services at OTPs. In order to update the valuation for HCPCS codes G2086 and G2087, we are proposing to increase the current payment rate to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 (*Psychotherapy, 45 minutes with patient*), rather than CPT code 90832 (*Psychotherapy, 30 minutes with patient*). The current work RVU assigned to CPT code 90834 is 2.24, compared to the work RVU assigned to CPT code 90832, which is 1.70, which results in a difference of 0.54 work RVUs. Because the bundled payments described by HCPCS codes G2086 and G2087 include two individual psychotherapy sessions per month, we are proposing to add 1.08 RVUs to the work value assigned to HCPCS codes G2086 and G2087, which results in a new work RVU of 8.14 for HCPCS code G2086 and 7.97 for HCPCS code G2087. We note that as described above, we are also proposing to update the work RVUs assigned to CPT code 90834 in this proposed rule. If our proposal to update the work RVUs for the standalone psychotherapy codes is finalized, CPT code 90834 would be assigned a work RVU of 2.35. In that case, our proposed update to HCPCS codes G2086 and G2087 would also reflect the updated work RVUs for 90834, and would result in a work RVU of 8.36 for HCPCS code G2086 and a work RVU of 8.19 for HCPCS code G2087.

7. Comment Solicitation on Expanding Access to Behavioral Health Services

In recent years, we have made efforts to undertake rulemaking and establish policies to expand access to behavioral health services, consistent with the CMS Behavioral Health Strategy, which aims to strengthen quality and equity in behavioral health care; improve access to substance use disorders prevention, treatment, and recovery services; ensure effective pain treatment and management; improve mental health care and services; and utilize data for effective actions and impact.[44] We continue to be interested in hearing feedback regarding ways we can continue to expand access to behavioral health services. For example, we welcome feedback regarding ways to increase access to behavioral health integration (BHI) services, including the psychiatric collaborative care model; whether we could consider new coding to allow interprofessional consultation to be billed by practitioners who are authorized by statute for the diagnosis and treatment of mental illness; intensive outpatient (IOP) services furnished in settings other than those addressed in the CY 2024 OPPS proposed rule; and how to increase psychiatrist participation in Medicare given their low rate of participation relative to other physician specialties. Additionally, we are seeking comment on whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, or whether existing payment mechanisms are sufficient to support furnishing such interventions when indicated.

We welcome comments from the public on these topics as well as any other ways we might consider expanding access to behavioral health services for Medicare beneficiaries.

8. Request for Information on Digital Therapies, Such as, But Not Limited to, Digital Cognitive Behavioral Therapy

The widespread adoption and use of software technologies, including, but not limited to digital therapeutics, is creating new ways to treat patients. In recent years, the Food and Drug Administration (FDA) has reviewed and cleared several mobile medical applications (''apps'') that have been

[44] *https://www.cms.gov/cms-behavioral-health-strategy.*

shown to demonstrate a reasonable assurance of safety and effectiveness for addressing a variety of health conditions including sleep disorders disturbances and substance use disorders. These breakthrough devices include apps for depression and anxiety. Our understanding is that these mobile medical apps generally require a prescription or referral from a clinician and are used for specific medical purposes rather than general wellness and education.

As technologies have evolved, we have sought public comment and expanded Medicare payment under Part B for use of technologies in remote monitoring of treatment and physical health. Beginning in 2018, CMS began making separate payment for the services described by CPT code 99091, which paid for collection and interpretation of physiologic data digitally stored and/or transmitted to the practitioner. Beginning in 2019, we began paying for additional new remote physiologic monitoring (RPM) codes.

We have continued to improve and expand payment for remote treatment and monitoring in subsequent years. In 2022, we began paying for a new class of CPT codes (98975, 98980, and 98981) for Remote Therapeutic Monitoring (RTM) in addition to RPM, which enabled reimbursement of monitoring of non-physiologic data, to help ensure Medicare beneficiaries have access to these services. RTM is currently limited to monitoring respiratory system status, musculoskeletal status, and therapy adherence, or therapy response (87 FR 69647). However, we continue to add, clarify, and refine payment for RTM codes.

In the CY 2023 PFS final rule (87 FR 69645), we finalized a new RTM code for supply of a device for cognitive behavioral therapy monitoring (CPT Code 989X6 *Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily)*) *recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days).* In that rule, we noted specialty societies indicated the technologies for this service are still evolving, and as a result, there were no invoices for devices specific to the cognitive behavioral therapy monitoring services described by the code that could be shared. We accepted the RUC recommendation to contractor price CPT code 989X6, a PE-only device code. We stated we would work with Medicare Administrative Contractors (MACs) to better understand the devices and device costs they encounter as they review claims for payment for the new cognitive behavioral monitoring code.

For both RPM and RTM codes, the device used must meet the FDA definition of a device as described in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA). As we continue to gather information on how remote monitoring services are used in clinical practice and experience with coding and payment policies for these codes, we request information on the following areas to improve our understanding of the opportunities and challenges related to our coverage and payment policies, as well as claims processing, as we consider the need for further practitioner education, program instructions, and guidance, or potential future rulemaking regarding these services.

- How do practitioners determine which patients might be best served by digital therapeutics? How do practitioners monitor the effectiveness of prescribed interventions, such as, but not limited to, for their patients on an ongoing basis once the intervention has begun?
- We seek comment and real-life examples where digital cognitive behavioral therapy or other digital enabled therapy services are used by clinicians, and how the technology is imbedded in various practice models. For example, how is the patient evaluated and/or how is the treating clinician involved in the services received when the patient participates in digital cognitive behavioral therapy?
- What standards have interested parties developed or consulted to ensure the physical safety and privacy of beneficiaries utilizing digital cognitive behavioral therapy (CBT) and/or other digital therapeutics for behavioral health?
- What are effective models for distribution/delivery of digital therapeutics, such as prescription digital mental health therapy products to patients? What best practices exist to ensure that patients have the necessary support and training to use applications effectively?
- What practitioners and auxiliary staff are involved in furnishing RPM and RTM services, including training patients on its use, and to what extent is additional training or supervision of auxiliary staff necessary to provide an appropriate for and/or recommended standard of care in the delivery of these services?
- How are data that are collected by the technology maintained for recordkeeping and care coordination?
- What information exists about how an episode of care should be defined, particularly in circumstances when a patient may receive concurrent RTM or digital CBT services from two different clinicians engaged in separate episodes of care?
- We noted in previous rulemaking that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected. We seek information on the type and frequency of circumstances that involve multiple medical devices and multiple clinicians. How might allowing multiple, concurrent RTM services for an individual beneficiary affect access to health care, patient out-of-pocket costs, the quality of care, health equity, and program integrity?
- Do interested parties believe digital CBT could be billed using the existing remote therapeutic monitoring codes described by CPT codes 98975, 98980, and 98981? What impediments may exist to using these codes for digital CBT?
- In the past, commenters generally supported the concept of a generic RTM device code, and offered a wide variety of possible use cases, including where FDA approved devices and devices that have gone through other premarket pathways exist for the purpose of monitoring various conditions that do not meet the current scope of the existing RTM codes.

++ What are the advantages and disadvantages of a generic RTM device code, versus specific RTM codes?

++ Would generic device codes undermine or stall progress toward a wider set of specific codes that would provide less ambiguity on reimbursement?

++ How might generic RTM codes for supply of a device be valued given the broad array of pricing models?

- What scientific and clinical evidence of effectiveness should CMS consider when determining whether digital therapeutics for behavioral health are reasonable and necessary?
- What aspects of digital therapeutics for behavioral health should CMS consider when determining whether it fits into a Medicare benefit category, and which category should be used?
- If CMS determines the services fit within an existing Medicare benefit category or if other coverage requirements are met, what aspects of delivering digital cognitive based therapy services should be considered when determining potential Medicare payment? Under current practice models, are these products used as

incident-to supplies or are they used independent of a patient visit with a practitioner? If used independently of a clinic visit, does a practitioner issue an order for the services?

- Are there barriers to digital CBT reaching underserved populations, and would a supervision requirement impact access to digital CBT for underserved populations?
- What strategies, if any, within the digital therapeutics for behavioral health support disadvantaged/hard to reach populations in advancing equity in health care services?
- What are some potential considerations for protecting the privacy and confidentiality of the patient population in digital therapeutics, including compliance with State behavioral health privacy requirements?

K. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') In the CY 2023 PFS final rule (87 FR 69663 through 69688), we identified certain clinical scenarios where payment is permitted under both Medicare Parts A and B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act.

The regulation at § 411.15(i)(3)(i) includes examples of services for which payment can be made under Medicare Parts A and B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related to the clinical success of, certain other covered services (hereafter in this section, ''inextricably linked to other covered services'').

Recognizing that there may be other instances where covered services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, we are proposing to expressly identify other instances where dental services are inextricably linked to other covered services such that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. At the same time, we recognize that there are dental services that are not inextricably linked to other covered services. In these instances, we continue to believe that Medicare payment is precluded by section 1862(a)(12) of the Act, except when, due to the patient's underlying medical condition and clinical status or the severity of the dental procedure, hospitalization is required; and that in those instances, the Medicare Part A exception provided under section 1862(a)(12) of the Act would apply.

In the CY 2023 PFS final rule (87 FR 69682, 69685, 69687), we also established a process for the public to submit additional dental services that may be inextricably linked to other covered services for our consideration and review, and finalized a policy to permit payment for certain dental services, such as dental examinations and necessary treatment, prior to or contemporaneously with the treatment of head and neck cancers, beginning in CY 2024.

We are proposing to codify in section § 411.15(i)(3)(i)(A) additional policies to permit payment for certain dental services that are inextricably linked to, and substantially related and integral to, the clinical success of, other covered services. We are also proposing to make non-substantive technical changes to improve clarity of the regulation text.

b. Other Medical Services for Which Dental Services May Be Inextricably Linked

In the CY 2023 PFS final rule, we discussed whether we should specify that payment can be made under Medicare Parts A and B for certain dental services prior to the initiation of immunosuppressant therapy, joint replacement procedures, or other surgical procedures. We stated that we remain committed to exploring the inextricable link between dental and covered services associated with immunosuppressant therapy, joint replacement surgeries, and other surgical procedures, and that we welcomed continued engagement with the public to review the clinical evidence to determine whether certain dental services were inextricably linked to covered services (87 FR 69668 and 69680 through 69686).

We partnered with researchers at the Agency for Healthcare Research and Quality (AHRQ) to consider the relationship between dental services and specific covered services, and review available clinical evidence regarding the relationship between dental services and medical services in the treatment of cancer using chemotherapeutic agents, which may lead to more clinically severe infections and often involve immunosuppression in patients. [45] [46] The AHRQ report[47] regarding dental services and the link between medical services is available at *https://effectivehealthcare.ahrq.gov/products/receiving-chemotherapy-cancer/rapid-review.* For example, it is generally understood that many chemotherapeutic agents used in the treatment of cancer target rapidly proliferating cells (which include those cells found in healthy tissue, like the oral mucosa). This targeting of rapidly reproducing cells in the oral mucosa can lead to the development of oral mucositis, which can negatively affect individuals with periodontitis and other dental conditions more severely, especially when they are exposed to higher doses/duration of chemotherapy.[48] Another example of a dental-related issue resulting from covered services that are immunosuppressive in nature is medication-related osteonecrosis of the jaw (MRONJ). MRONJ may occur as an adverse effect when patients with cancer receive specific covered services, such as high-dose antiresorptive and/or antiangiogenic drug therapy (for example, high doses of bisphosphonates or drugs like denosumab used to treat osteoporosis) or bone-modifying therapy in conjunction with their chemotherapy regimen. Patients with existing dental disease are most at risk for developing MRONJ secondary to bone-modifying therapy. MRONJ complicates the cancer treatment and can lead to reduced survival rates up to 3 years post-

[45] Immunosuppression describes an impairment of the cells of a patient's immune system and a reduction in their ability to fight infections and other diseases.

[46] National Cancer Institute. NCI Dictionary of Cancer Terms. 2019. Available at *https://www.cancer.gov/publications/dictionaries/cancer-terms.*

[47] Hickam DH, Gordon CJ, Armstrong CE, Coen MJ, Paynter R, Helfand M. The Efficacy of Dental Services for Reducing Adverse Events in Those Receiving Chemotherapy for Cancer. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23–EHC021. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: *https://doi.org/AHRQEPCRAPIDDENTALCANCER.*

[48] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573–0002.2017.03.*

treatment.[49] Dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[50] Further, AHRQ noted that there is abundant worldwide experience and related standards of care in the management of patients whose medical conditions require chemotherapy regimens that induce immunosuppression, and that this experience has led to an understanding of how improved dental care potentially can reduce the incidence of serious infections and improve overall patient outcomes.

The AHRQ examined the effects of dental care prior to treatment on the success of medical services for patients receiving chemotherapy regimens (primary medical service) in the treatment of cancer (primary medical illness). As part of this analysis, AHRQ identified 26 primary research studies, 7 systematic reviews, and 5 practice guidelines that outline benefits and harms of pre-treatment dental services and their effects on cancer chemotherapy regimens. The studies were selected using specific inclusion criteria: a sample of patients beginning cancer treatment within two months; targeted dental services occurring prior to cancer treatment; outcomes data, such as rates of serious adverse events, quality of life, cancer relapse rates, mortality, or adherence to cancer treatment; and a minimum sample size of 10 patients.

The 26 primary research studies identified by AHRQ included prospective cohort studies, retrospective cohort studies, randomized controlled trials, and registry-based studies. From this group of studies, AHRQ found evidence to support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the covered services, as well as requiring fewer emergency treatments.[51] [52] There was further evidence found in systematic reviews that showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2–3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[53] They note that treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (often life-threatening) bacterial and fungal infections, and that the route of entry of these offending bacteria can be the mouth. AHRQ also analyzed several clinical practice guidelines that supported a dental evaluation/treatment before initiating chemotherapy so that any oral complications could be mitigated prior to initiating care to treat the cancer. [54] [55] [56]

c. Submissions Received Through Public Submission Process

In the CY 2023 PFS final rule, we stated that we believed there may be additional clinical scenarios we have not yet identified under which Medicare payment could be made for certain dental services on the basis that dental services are inextricably linked to other covered services (87 FR 69686). In order to ensure we are appropriately considering other potential clinical scenarios that may involve such dental services, we finalized an annual public process, including notice and comment rulemaking, whereby interested parties can submit recommendations for other clinical scenarios for potential inclusion on the list of dental services for which payment can be made under § 411.15(i)(3)(i).

Through this process, we stated that we would review clinical evidence to assess whether there is an inextricable link between certain dental and covered services because the standard of care for that medical service is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment (87 FR 69685). We also stated that, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services. (87 FR 69666) As such, we requested that documentation accompanying recommendations should include medical evidence to support that certain dental services are inextricably linked to certain other covered services. Specifically, we requested that the medical evidence should:

(1) Provide support that the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure;

(2) Be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the covered services; and

(3) Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient). (87 FR 69686)

[49] Corraini, P., Heide-Jørgensen, U., Schiødt, M., Nørholt, S. E., Acquavella, J., Sørensen, H. T., & Ehrenstein, V. (2017). Osteonecrosis of the jaw and survival of patients with cancer: a nationwide cohort study in Denmark. Cancer medicine, 6(10), 2271–2277. *https://doi.org/10.1002/cam4.1173.*

[50] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions -a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573–0002.2017.03.*

[51] Watson EE, Metcalfe JE, Kreher MR, et al. Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397-e405. doi: *https://dx.doi.org/10.1200/OP.20.00107. PMID: 32609586.*

[52] Owosho AA, Liang STY, Sax AZ, et al. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440–5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003. PMID: 29580668.*

[53] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, et al. Required time for pre-oncological dental management—A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116. PMID: 36115328.*

[54] Elad S, Cheng KKF, Lalla RV, et al. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. Cancer. 2020 Oct 1;126(19):4423–31. doi: *https://dx.doi.org/10.1002/cncr.33100. PMID: 32786044.*

[55] Yarom N, Shapiro CL, Peterson DE, et al. Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270–90. doi: *https://dx.doi.org/10.1200/JCO.19.01186. PMID: 31329513.*

[56] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

We stated that interested parties should submit medical evidence to support, for the recommended clinical scenario, the inextricable link between certain dental services and other covered services by providing any of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686, 69687).

We stated that we intended to use the PFS annual rulemaking process to discuss public submissions when considering whether the recommended dental services associated with certain clinical scenarios should be considered outside the scope of the general preclusion on payment for dental services under section 1862(a)(12) of the Act because they are inextricably linked to other covered services. We continue to believe that public feedback is important, especially when considering Medicare payment for dental services that may benefit the clinical outcomes for certain covered services. We believe that using our annual notice and comment rulemaking process to discuss submitted recommendations will allow the public to comment and submit further medical evidence to assist us in evaluating whether certain dental services furnished in certain clinical scenarios would meet the standard to permit Medicare payment for the dental services. Under the public process established in the CY 2023 PFS final rule, recommendations received by February 10th of a calendar year would be reviewed for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. The deadline for submissions for potential consideration for CY 2024 rulemaking was February 10, 2023. We received eight submissions from various organizations on or before February 10, 2023. We received one submission after the deadline that presented nominations for covered services that have already been addressed by this payment policy.

Submissions included recommendations for payment under Medicare Parts A and B of dental services prior to covered services associated with the treatment of cancer (chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, bone-modifying agents or antiresorptive therapy), total joint arthroplasty, all cardiovascular procedures, diabetes treatment, treatment for sickle-cell anemia and hemophilia, and systemic autoimmune diseases. Additionally, many submissions recommended that CMS refine certain terminology surrounding previously finalized policies, specifically around whether payment can be made for dental services furnished during and after the performance of certain covered services.

Several submissions recommended that Medicare make payment under Parts A and B for dental services prior to covered services associated with the treatment of patients with leukemia and lymphoma, as well as other cancers. Most submitting organizations stated that, by examining and addressing the oral health of the patient prior to the initiation of chemotherapy in the treatment of cancer, with or without radiation, oral complications could be appropriately addressed or prevented that would improve the clinical success of the overall cancer treatment. Submissions also recommended Medicare payment under Parts A and B for dental services before, during, and after CAR T-cell therapy and other lymphodepleting covered services (lymphodepleting therapy involves a short course of chemotherapy that targets T-cells, preconditioning the body prior to enhance treatments like CAR T-cell therapy). These submissions stressed the need to detect early and monitor dental issues and to avoid the increased risk of related infections and complications.

Most submissions stated that medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of antiresorptive and/or antiangiogenic drug therapy used to help manage the treatment of cancer. Several recommended that Medicare make payment under Parts A and B for dental services for patients where high-dose bisphosphonate therapy for cancers is indicated, such as blood and solid tumor cancers and metastatic cancers associated with risk of osteonecrosis of the jaw. These submissions recommended payment of dental services prior to and during antiresorptive therapy or prior to, during, and after the use of bone-modifying drugs. One provided references that support the provision of dental services to prevent, or as part of treatment for MRONJ. Another submission stated that the risk of MRONJ is significantly greater in patients receiving antiresorptive therapy in connection with cancer treatment compared to patients receiving antiresorptive therapy for osteoporosis. However, the submitter stated that the combination of poly-pharmaceutical management of cancer patients and related immunosuppression are risk factors for MRONJ without exposure to antiresorptive agents, and that it would be difficult to identify a single medication as the etiologic agent for MRONJ in case reports or mini-case series. The submitter stated that prevention of MRONJ would be the clinical gold standard.

One submission also recommend that Medicare make payment under Parts A and B for dental services prior to all cardiovascular procedures. In their view, the provision of dental services to reduce risk of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. They cited a literature review in support of the need for screening and treatment for oral/dental infections prior to cardiac surgery. This submission did not recommend dental services prior to a specific cardiovascular procedure; rather, it recommended dental services prior to all cardiovascular procedures. The literature review they cited, (which we discuss below at section II.K.3. of this proposed rule) noted that there was a mixture of medical literature to support the performance of dental services prior to all cardiac procedures in part because such cardiovascular procedures are more urgent or emergent than elective.

One submission recommended that Medicare make payment under Medicare Parts A and B for dental services prior to joint replacement surgeries, specifically total knee and hip arthroplasty. The submitting organization stated that the provision of dental services prior to or contemporaneously with joint replacement surgeries may result in more rapid healing and quicker rehabilitation, especially if a known dental infection could be addressed and potentially prevent surgical and rehabilitation complications for the patient. However, the submission acknowledged that there is no consensus on whether performing dental services prior to joint replacement surgeries improves the clinical outcomes of the medical service, or whether it is typical in practice to furnish dental services before joint replacement procedures.

Other submissions recommended Medicare make payment for dental services for patients diagnosed with a

specific condition(s), such as patients with poorly controlled diabetes mellitus, or individuals living with sickle cell disease (SCD) or hemophilia.

Submissions also recommended Medicare payment for dental services for persons affected by systemic autoimmune disease. They argued that dental services are an essential component of medical treatment for these individuals who are at much higher risk of advanced dental decay, dental loss, and/or gum disease. They stated that reducing oral infection of the mucosa, teeth, and gums; oral inflammation; and tooth loss through consistent oral management reduces the systemic impact that these dental conditions have on a patient's systemic autoimmune disease. One submission stated that oral health disparities disproportionately affect members of racial or ethnic minority groups, which they offered is most pronounced in populations aged 65 and older. Another presented their proposal to bridge the gap in health equity and to improve the health outcomes for those ages 65 and older living with autoimmune diseases.

We thank all those who submitted recommendations for clinical scenarios for which they believe Medicare payment for dental services would be consistent with the policies we codified and clarified in the CY 2023 PFS final rule under which Medicare payment could be made for dental services when inextricably linked to other covered services. We continue to encourage interested parties to engage with us regularly and to submit recommendations for our consideration of additional clinical scenarios where dental services may be inextricably linked to specific covered services. As stated earlier, interested parties should provide evidence to support or refute that at least one of the three criteria listed above for submissions is met. Furthermore, submissions should focus on the inextricably linked relationship between dental and medical services, not a specific medical condition, and whether it is not clinically advisable to move forward with the medical service without having first completed the dental service(s). We remind readers that, to be considered for purposes of CY 2025 PFS rulemaking, submissions through our public process for recommendations on payment for dental services should be received by February 10, 2024, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov*. Interested parties should include the words ''dental recommendations for CY 2025 review'' in the subject line of their email submission to facilitate processing. We stress to submitters that recommendations must include at least one of the types of evidence listed earlier when submitting documentation to support the inextricable link between specified dental services and other covered services. We note that we may also consider recommendations that are submitted as public comments during the comment period following the publication of the PFS proposed rule.

2. Proposed Additions to Current Policies Permitting Payment for Dental Services Inextricably Linked to Other Covered Services

Under our current policy, we have identified several clinical scenarios where dental services are inextricably linked to a primary medical service that is covered by Medicare, such that Medicare payment for the dental services is not precluded by section 1862(a)(12) of the Act. After further review of current medical practice, and through internal and external consultations and consideration of the submissions received through the public process established in the CY 2023 PFS final rule (87 FR 69669), we believe there are additional circumstances that are clinically similar to the scenarios we codified in our regulation at § 411.15(i)(3)(i) as examples of clinical scenarios under which Medicare payment may be made for certain dental services because they are inextricably linked to other covered medical service(s).

In the case of the proposed primary, covered services, we believe that dental services are inextricably linked to, and substantially related and integral to the clinical success of, the proposed covered services because such dental services serve to mitigate the substantial risk to the success of the medical services, due to the occurrence and severity of complications caused by the primary medical services, including infection. Additionally, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services or if the dental services are considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment. As such, we believe the dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, the following medical services, and the statutory dental exclusion would not apply:

(1) Chemotherapy when used in the treatment of cancer;

(2) CAR T-Cell therapy, when used in the treatment of cancer; and

(3) Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

As such, we propose to amend our regulation at § 411.15(i)(3)(i)(A) to permit payment under Medicare Parts A and Part B for:

(1) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered: chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with: chemotherapy when used in the treatment of cancer, CAR T-cell therapy when used in the treatment of cancer, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Furthermore, we propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as currently described in our regulation at § 411.15(i)(3)(ii).

a. Dental Services Inextricably Linked to Chemotherapy Services When Used in the Treatment of Cancer

In the CY 2023 PFS final rule (87 FR 69663 through 69688), and as described in section II.K.1 of this proposed rule, we stated that we would continue to study the relationship between dental care and medical services that cause immunosuppression in patients, and the risk of dental infection and complications that arise because of the treatment-induced immunosuppression. As discussed in section II.K.1 of this proposed rule, we received submissions through the public process and comments on the CY 2023 PFS proposed rule requesting that Medicare payment should be permitted under Parts A and B for dental services when medical services that cause

immunosuppression are being provided to treat a variety of medical conditions.

Commenters asserted that immunocompromised patients are at an increased risk of serious infection that can lead to severe conditions (87 FR 69683). We stated that we agreed with commenters that individuals who are immunocompromised may be prone to serious infection, and that we would continue to consider feedback and the clinical literature provided by interested parties to determine whether there are other clinical scenarios, such as the initiation of immunosuppressive therapies, where Medicare payment should not be excluded for dental services under section 1862(a)(12) of the Act, because the services are inextricably linked to certain other covered services.

In the CY 2023 PFS final rule (87 FR 69681) and as discussed in section II.K.2 of this rule, we stated that we were finalizing a policy for CY 2024 that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to or contemporaneously with Medicare-covered treatments for head and neck cancer. We stated that removing infections in the oral cavity is necessary to prepare patients for treatment and is inextricably linked to the clinical success of treatment for cancers of the head and neck. Additionally, as described in the comments received on the CY 2023 PFS proposed rule and summarized in the CY 2023 PFS final rule (87 FR 69683), commenters suggested that the patient population with any cancer receiving chemotherapy treatments required dental services that were linked to the clinical success of the completion of the chemotherapy treatment. They indicated that immunocompromised patients, such as individuals with blood cancers (leukemia and lymphoma) or other types of cancers, are at increased risk of serious infection that can lead to severe complications and adverse outcomes. Commenters provided information showing that chemotherapy drugs used for treatment of head and neck cancers can have many side effects, including sores and lesions in the mouth and throat tissues, difficulty swallowing, bleeding in the mouth, and tooth decay. Additionally, commenters stated that, because chemotherapy reduces the body's ability to fight opportunistic infections, patients who begin chemotherapy with untreated infections (including infections in the oral cavity) are at risk of developing a number of complications, ranging from fungal or viral infections of the mouth and throat to systemic infections or fatal sepsis. Commenters observed that complications arising from untreated infections could cause treatment interruptions which could compromise the success of the treatment and the patient's outcomes. One commenter observed that the need for removing oral infection prior to starting chemotherapy is analogous to the rationale for providing oral care prior to renal transplant, and thus (like a dental exam prior to renal transplant) should be considered substantially related and inextricably linked to the clinical success of the treatment. Commenters recommended that patients receiving chemotherapy for head or neck cancer receive a dental exam and stabilization, if applicable. Several commenters noted that providing an oral exam prior to starting chemotherapy is the standard of care in many cancer centers (87 FR 69681 through 69683).

Additionally, in the CY 2023 PFS final rule (87 FR 69682), we stated that many commenters recommended that we permit payment under Medicare Parts A and B for dental services prior to treatment for all types of cancer patients instead of just those with head and neck cancers; commenters suggested that the linkage between the medical services (chemotherapy, with or without radiation) and dental services was the same whether the medical services are used to specifically treat head and neck cancers or other cancers. Commenters stated that the increased risk of infections and sepsis among cancer patients could constitute major health setbacks that are costly to treat and can compromise the success of the cancer treatment. We reiterated that we would continue to review and evaluate information that supports the relationship between dental care and covered treatments for cancer (including treatments related to conditions not localized in the head, neck, or oral cavity), and have continued to study this issue.

We believe immunosuppression is commonly understood to be a suppression or reduction of the body's immune response, which can be caused by various factors that increase susceptibility to infections and an increased risk of developing certain types of conditions.[57] There is significant and abundant worldwide experience and research regarding the care of patients whose medical conditions require chemotherapy regimens that induce acute immunosuppression.[58] [59] The treatment of a broad range of malignancies often requires the use of chemotherapeutic agents that in turn suppress the body's production of white blood cells, thereby impairing the body's ability to resist serious (potentially life-threatening) infections. The route of entry of the offending pathogens can be the mouth.[60] [61] [62] Therefore, individuals receiving chemotherapy treatment for cancer who become immunosuppressed may be more susceptible to infection and other adverse events with serious consequences for the patient. We understand that medical services used in the treatment of cancer, such as chemotherapy, induce immunosuppression. As such, we believe that cancer patients being treated with chemotherapy represent an acutely-impacted, immunocompromised patient population due to the nature of the effects of such chemotherapy treatment. If dental or oral infections are left undetected or untreated in these patients, serious complications may occur, negatively impacting the clinical success of the medical services and outcomes for the patients. Moreover, the immunosuppression induced by the chemotherapy medical services in the treatment of cancer increases the likelihood and intensity of complications for the patient that could potentially jeopardize or impact the ability to complete the totality of the treatment across a normal course of treatment.[63] [64] If an oral or dental

[57] Abbas AK, Lichtman AH, Pillai S. Basic Immunology: Functions and Disorders of the Immune System. 5th edition. Philadelphia: Elsevier; 2016. Chapter 8, Immune Suppression.

[58] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7–13. doi: *https://dx.doi.org/10.1111/odi.13329*. PMID: 32166855.

[59] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085–92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896*. PMID: 25024068.

[60] Mirowski GW, Bettencourt JD, Hood AF. Oral infections in the immunocompromised host. Semin Cutan Med Surg. 1997 Dec;16(4):249–56. doi: *https://dx.doi.org/10.1016/s1085-5629(97)80013-2*. PMID: 9421215.

[61] Greenberg MS, Cohen SG, McKitrick JC, et al. The oral flor as a source of septicemia in patients with acute leukemia. Oral Surg Oral Med Oral Pathol. 1982 Jan;53(1):32–6. PMID: 6948251.

[62] King A, Irvine S, McFadyen A, et al. Do we overtreat patients with presumed neutropenic sepsis? Postgrad Med J. 2022 Nov;98(1165):825–9. doi: *https://dx.doi.org/10.1136/postgradmedj-2021-140675*. PMID: 34611037.

[63] Spijkervet FKL, Schuurhuis JM, Stokman MA, et al. Should oral foci of infection be removed before the onset of radiotherapy or chemotherapy? Oral Dis. 2021 Jan;27(1):7–13. doi: *https://dx.doi.org/10.1111/odi.13329*. PMID: 32166855.

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infection is not properly diagnosed and treated prior to and/or during the chemotherapy in the treatment of cancer, which suppresses the immune system, there may be an increased risk for local and systemic infections from odontogenic sources; and furthermore, the successful completion of that treatment could be compromised. Additionally, if such an infection is not treated, then there is an increased likelihood of morbidity and mortality resulting from the spreading of the local infection to sepsis [65] [66]

Individuals undergoing chemotherapy services used in the treatment of cancer who become immunosuppressed by the treatment may also experience oral mucositis, which often facilitates entry of oral bacteria into the body, potentially increasing the risk of infection for the patient and compromising the chemotherapy regimen. The risk of mucositis and potential complications to the clinical success of medical services for cancer treatment is similar to the risk for patients receiving Hematopoietic Stem Cell Transplants (HSCT) and bone marrow transplants,[67] [68] for which we finalized payment for certain dental services prior to these medical services (87 FR 69677). These potential complications, resulting from the combined immunosuppression and mucositis caused by the chemotherapy services, present a risk to the patient and the success of the medical chemotherapy regimen, unless mitigated by the provision of dental services. Additionally, as described above, evidence found in systematic reviews showed a possible increased incidence of oral mucositis when dental treatment is not administered at least 2–3 weeks prior to initiation of cancer treatment, further complicating the totality of services a patient received to treat their cancer.[69]

Moreover, as described above in section II.K.1. of this proposed rule, dental services to identify and treat oral complications/comorbidities prior to and, sometimes, throughout chemotherapy treatment have been associated with improved outcomes for the patient receiving medical services in the treatment of cancer.[70] Additionally, as discussed in section II.K.1. of this proposed rule, research studies support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications (such as, oral mucositis and osteonecrosis) with the medical services, as well as requiring fewer emergency treatments.[71] [72]

Consequently, we believe that the evidence supports that the standard of care is such that one would not proceed with the chemotherapy when used in the treatment of cancer without performing the dental services, because the covered services would or could be significantly and materially compromised, such that clinical outcomes of the chemotherapy treatment could be compromised absent the provision of the inextricably-linked dental services.

As described in the CY 2023 PFS final rule (87 FR 69685), we noted that evidence to support the linkage between the dental and covered services could include information demonstrating that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to clear the patient of an oral or dental infection; or, in instances where a known oral or dental infection is present, the standard is such that the medical professional would not proceed with the medical service until the patient received the necessary treatment to eradicate the infection. Our review of relevant clinical practice guidelines demonstrated that multiple professional societies recommend the performance of dental services prior to the initiation of or during chemotherapy.[73] [74] For instance, the United Kingdom published a guideline for dental evaluation and treatment before and after treatments for head and neck cancer (5th edition of the UK Multi-Disciplinary Guidelines for Head and Neck Cancer), based on guidance from the National Institute for Health and Care Excellence (NICE) and expert recommendations: ''Preventive oral care must be delivered to patients whose cancer treatment will affect the oral cavity, jaws, salivary glands and oral accessibility.'' [75] Additionally, as described in the CY 2023 PFS final rule (87 FR 69680), several commenters provided data regarding the treatment of head and neck cancer that illustrated that conditions such as oral mucositis or osteonecrosis of the jaw that occur during the treatment may compromise the clinical success of the primary medical service (chemotherapy for the treatment of head and neck cancer), potentially leading to multiple hospitalizations, including systemic infections or fatal sepsis, if dental infections remained untreated.

We believe chemotherapy used in the treatment of cancer causes acute immunosuppression, causing significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn may lead to serious and imminent risks to the success of the primary medical procedures and treatments. These treatment-induced complications, including possible infection, prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy)

[64] Hanna N, Einhorn LH. Testicular cancer: a reflection on 50 years of discovery. J Clin Oncol. 2014 Oct 1;32(28):3085–92. doi: *https://dx.doi.org/10.1200/JCO.2014.56.0896*. PMID: 25024068.

[65] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[66] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May;2007 15(5):491–496. [PubMed: 17139495].

[67] Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of allogeneic hematopoietic stem-cell transplantation in patients with hematologic malignancies. Support Care Cancer May,2007 15(5):491–496. [PubMed: 17139495].

[68] Ruescher TJ, Sodeifi A, Scrivani SJ, Kaban LB, Sonis ST. The impact of mucositis on alpha-hemolytic streptococcal infection in patients undergoing autologous bone marrow transplantation for hematologic malignancies. Cancer 1998;82(11):2275–2281. [PubMed: 9610710].

[69] Mazzetti T, Sergio da Silva Santos P, Spindola Antunes H, et al. Required time for pre-oncological dental management—A rapid review of the literature. Oral Oncol. 2022 11;134:106116. doi: *https://dx.doi.org/10.1016/j.oraloncology.2022.106116. PMID: 36115328.*

[70] Poulopoulos A, Papadopoulos P, Andreadis D. Chemotherapy: oral side effects and dental interventions-a review of the literature. Stomatological Disease and Science. 2017; 1:35–49. *http://dx.doi.org/10.20517/2573-0002.2017.03.*

[71] Watson EE, Metcalfe JE, Kreher MR, et al. Screening for Dental Infections Achieves 6-Fold Reduction in Dental Emergencies During Induction Chemotherapy for Acute Myeloid Leukemia. JCO Oncol Pract. 2020 11;16(11):e1397–e405. doi: *https://dx.doi.org/10.1200/OP.20.00107. PMID: 32609586.*

[72] Owosho AA, Liang STY, Sax AZ, et al. Medication-related osteonecrosis of the jaw: An update on the memorial sloan kettering cancer center experience and the role of premedication dental evaluation in prevention. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018 May;125(5):440–5. doi: *https://dx.doi.org/10.1016/j.oooo.2018.02.003. PMID: 29580668.*

[73] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

[74] American Academy of Pediatric Dentistry. Dental management of pediatric patients receiving immunosuppressive therapy and/or head and neck radiation. The Reference Manual of Pediatric Dentistry. Chicago, Ill.; 2022:507–16.

[75] Butterworth C, McCaul L, Barclay C. Restorative dentistry and oral rehabilitation: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016 May;130(S2):S41–S4. PMID: 27841112.

and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of the Medicare covered chemotherapy when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment and therefore the dental services are integral and inextricably linked to these medical services, and the statutory dental exclusion would not apply.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to chemotherapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present substantial risk to the success of chemotherapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered services.

We also seek comment on whether we should consider radiation therapy in the treatment of cancer more broadly (not in conjunction with chemotherapy, and not in relation to head and neck cancer treatment) as medical services that may be inextricably linked to dental services. We do not believe that radiation therapy alone necessarily leads to the same level of treatment-induced immunosuppression as for cancer patients receiving chemotherapy since radiation specifically targets malignant cells and has more targeted and localized effects on the body as compared to system-wide immunosuppression effects of chemotherapy for cancer treatment. However, we seek comment on whether dental services prior to radiation therapy in the treatment of cancer, when furnished without chemotherapy, such as second line therapy for metastasized cancer in the head and neck, would be inextricably linked to the radiation therapy services, and therefore payable under Medicare Parts A and B.

In summary, after consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of chemotherapy services, we believe that there is an inextricable link between certain dental and chemotherapy services when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service(s) because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the chemotherapy services when used in the treatment of cancer. Chemotherapy services when used in the treatment of cancer cause immunosuppression which may lead to significant oral complications and adverse events, including the possibility of an oral or dental infection, which in turn lead to serious and imminent risks to the success of the primary medical procedures and treatments. The complications, including possible infection, may prevent the ability to both initiate and proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy) such that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. In the case of chemotherapy services when used in the treatment of cancer, dental services serve to mitigate the likelihood of occurrence and severity of complications caused by the primary medical services, including infection, and consequently the dental services facilitate the successful completion of the prescribed course of treatment. Therefore, we believe the dental services are integral and inextricably linked to the chemotherapy when used in the treatment of cancer, and the statutory dental exclusion under section 1862(a)(12) of the Act would not apply.

We are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we propose to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered chemotherapy when used in the treatment of cancer; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer. We seek comments on all aspects of this proposal. Additionally, we note that we are proposing to make payment for dental services that are inextricably linked to chemotherapy used in the treatment of cancer with or without the use of other therapy types, including radiation therapy in the treatment of cancer. That is, this proposal is not meant to be limited to cases where chemotherapy in the treatment of cancer is provided without the use of other therapies. We seek comment on this aspect of the proposal.

b. Dental Services Inextricably Linked to CAR T-Cell Therapy, When Used in the Treatment of Cancer

In the CY 2023 PFS final rule (87 FR 69677), commenters stated that individuals receiving CAR T-cell treatment for cancer may also require dental services, suggesting that these dental services are inextricably linked to covered CAR T-cell medical services, asserting that dental and oral services improve clinical outcomes for these types of medical services. We also received submissions through the public process providing evidence to show that dental services are inextricably linked to the clinical success of CAR T-cell medical services and other lymphodepleting therapy when used in the treatment of cancer. The submissions stated that, because CAR T-cell medical services cause a patient to be immunosuppressed, an untreated oral or dental infection could complicate or compromise the clinical outcome of the CAR T-cell medical service. Two submissions cited research indicating that patients undergoing CAR T-cell therapy and other lymphodepleting therapy, which is a short course of chemotherapy for the purpose of killing off a portion (or all) of the patient's own lymphocytes and/or other white blood cells prior to an immunotherapy or a bone marrow transplant, experience a higher infection risk in the first 100 days post-

treatment.[76] Submitters also stressed the need to detect early and monitor for dental issues during CAR T-cell therapy in order to avoid the increased risk of related infections and complications. These submissions also highlighted that clinical practice guidelines recommend dental services prior to initiating the CAR T-cell therapy and other lymphodepleting therapy in order to eliminate any sources of infection before and during treatment.[77] [78] [79] [80] [81]

After consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of CAR T-cell therapy, we are persuaded that dental services to diagnose and treat infection prior to CAR T-cell therapy are inextricably linked to the clinical success of CAR T-cell therapy, and that these services also represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the inpatient or outpatient setting, such as prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures. We believe there is an inextricable link between dental and CAR T-cell therapy when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the CAR T-cell therapy when used in the treatment of cancer.

We believe that proceeding without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to (CAR) T-cell therapy when used in the treatment of cancer could lead to systemic infection or sepsis, as well as other complications for the patient. We also believe that an oral or dental infection could present substantial risk to the success of the (CAR) T-cell therapy when used in the treatment of cancer, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with (CAR) T-cell therapy when used in the treatment of cancer are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services. As such, we are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we propose to amend the regulation to include a dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered CAR T-cell therapy when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, CAR T-cell therapy when used in the treatment of. We seek comments on all aspects of this proposal.

We also seek comment on whether we should add as an example of dental services for which payment may be made under Medicare Parts A and B other types of lymphodepleting medical services used for cancer treatment, in addition to those used in conjunction with CAR T-cell therapy for cancer treatment. Commenters specifically stated that CAR T-Cell therapies constituted lymphodepleting therapies, and we believe there may be other immunotherapies that may have a similar lymphodepletion component, but we received no specific information regarding such therapies. Evidence submitted by the public through the finalized public submission process indicates that treatment-induced immunosuppression may also occur with lymphodepleting medical services, and that complications caused by the treatment-induced immunosuppression, including possible infection, may prevent the ability to proceed with the primary, covered medical service (that is, lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing the effectiveness of the therapy) and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection. However, we request comment on what specific medical services also involve lymphodepletion and should therefore be considered in addition to CAR T-cell therapy. We also request additional information regarding how those specific services might be impacted by dental infections/conditions. We note that if we receive compelling clinical evidence, we may finalize in the CY 2024 PFS final rule additional clinical scenarios, such as dental services prior to other types of specific lymphodepleting medical services where the treatment may induce immunosuppression for patients with cancer and the standard of care would be to not proceed with the medical services without having first complete the dental services, where payment could be made under Medicare Part A or Part B. We are seeking comment on whether there is a significant quality of care detriment if certain dental services are not provided prior to these other types of lymphodepleting medical services, and if so, we request a description of that systematic evidence. Specifically, similar to the evidence we requested in the CY 2023 PFS proposed rule, we are looking for medical evidence that the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the implant and interfered with the implant to the

[76] Wudhikarn K, Palomba ML, Pennisi M, Garcia-Recio M, Flynn JR, Devlin SM, Afuye A, Silverberg ML, Maloy MA, Shah GL, Scordo M, Dahi PB, Sauter CS, Batlevi CL, Santomasso BD, Mead E, Seo SK, Perales MA. Infection during the first year in patients treated with CD19 CAR T cells for diffuse large B cell lymphoma. Blood Cancer J. 2020 Aug 5;10(8):79. *doi: 10.1038/s41408–020–00346–7.* PMID: 32759935; PMCID: PMC7405315.

[77] Elad S, Raber-Durlacher JE, Brennan MT, Saunders DP, Mank AP, Zadik Y, Quinn B, Epstein JB, Blijlevens NM, Waltimo T, Passweg JR, Correa ME, Dahllöf G, Garming-Legert KU, Logan RM, Potting CM, Shapira MY, Soga Y, Stringer J, Stokman MA, Vokurka S, Wallhult E, Yarom N, Jensen SB. Basic oral care for hematology-oncology patients and hematopoietic stem cell transplantation recipients: a position paper from the joint task force of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and the European Society for Blood and Marrow Transplantation (EBMT). Support Care Cancer. 2015 Jan;23(1):223–36. Epub 2014 Sep 5. PMID: 25189149; PMCID: PMC4328129. *doi: 10.1007/s00520–014–2378–x.*

[78] University of Michigan, CAR–T Cell Patient Dental Clearance Instructions, no date. CellularTherapyDentalForm.pdf (*umich.edu*).

[79] Guideline on dental management of pediatric patients receiving chemotherapy, hematopoietic cell transplantation, and/or radiation. Pediatr Dent, 2008; 30(7 Suppl):219–225.

[80] McGuire DB, Correa ME, Johnson J, Wienandts P. The role of basic oral care and good clinical practice principles in the management of oral mucositis. Support Care Cancer, 2006; 14(6):541–547. *doi:10.1007/s00520–006–0051–8 8.*

[81] Vendrell Rankin K, Jones DL, Redding SW (Eds.), Oral Health in Cancer Therapy: A Guide for Health Care Professionals [3rd edition], Baylor Oral Health Foundation and the Cancer Prevention and Research Institute of Texas, 2008. *https://doi.org/10.1002/9781118416426.ch101.*

skeletal structure. If commenters are able to provide us with compelling evidence to support that a dental exam and necessary treatment prior to specific other lymphodepleting medical services where the treatment may induce immunosuppression for patients with cancer, would result in clinically significant improvements in quality and safety outcomes, for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, quicker rehabilitation for the patient, then we would consider whether such dental services may be inextricably linked to, and substantially related and integral to the clinical success of, the specific lymphodepleting medical services for patients with cancer.

c. Dental Services Inextricably Linked To Administration of High-Dose Bone-Modifying Agents (Antiresorptive Therapy) When Used in the Treatment of Cancer

As discussed above, submissions received through the public process we established in the CY 2023 PFS final rule stated that medication-related osteonecrosis of the jaw (MRONJ) is a serious complication of the administration of bone-modifying agents (such as bisphosphonates and denosumab, and other biosimilar agents) used when managing certain cancers.[82] MRONJ is a rare occurrence, multifactorial in nature, and can have the same clinical presentation in patients who have not been exposed to an antiresorptive medication.[83] that Medicare make payment under Parts A and B for dental services for patients where high-dose bisphosphonate therapy for cancers is indicated and recommended payment for dental services prior to and during antiresorptive therapy or prior to, during, and after the use of bone-modifying drugs. Additionally, in our internal review of clinical practice guidelines, we noted that one professional society provided recommendations regarding dental services prior to the initiation of, or during, the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Specifically, the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) and American Society of Clinical Oncology (ASCO) Clinical Practice Guideline[84] states that cancer patients should receive an oral care assessment (including a comprehensive dental, periodontal, and oral radiographic exam, when feasible) prior to initiating the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer in order to reduce complications and manage modifiable risk factors. We believe that this practice guideline demonstrate that the standard of care would be to address dental infections prior to proceeding with the covered medical procedure, including oral care assessments and the completion of medically necessary dental procedures prior to the start of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, especially as these dental concerns and/or procedures may relate to the cancer treatment and avoidance of MRONJ.

In summary, after consideration of clinical practice guidelines, recommendations provided by the public, and our analyses of the studies and research available regarding the connection between dental services and the clinical success of the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, we are proposing to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). We believe that there is an inextricable link between dental and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer because the standard of care is such that one would not proceed with the medical procedure or service without performing the dental service because the covered medical services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services and that dental services are a clinical prerequisite to proceeding with the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. Specifically, we propose to amend the regulation to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered the administration of Medicare-covered high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, administration of high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer. We seek comments on all aspects of this proposal.

We note that in the CY 2023 PFS final rule (87 FR 70225) and now codified in our regulation at § 411.15(i)(3)(i), we finalized that for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service, payment may be made under Medicare Parts A and B for services when furnished in either the inpatient or outpatient setting; therefore, we proposed that these provisions would apply to the proposed amendments to regulation at § 411.15(i)(3)(i) to allow for payment under Medicare Parts A and Part B in either the inpatient or outpatient setting. We further propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described in our regulation at § 411.15(i)(3)(ii).

If the proposed policies are finalized, we anticipate making conforming changes to the Medicare Benefit Policy Manual (IOM Pub. 100–02) to reflect the final changes or clarifications. Additionally, if finalized, we intend to issue educational and outreach materials to inform billing and payment for any policies finalized in the final rule We seek comments on these proposals.

d. Proposed Amendments to Regulations Regarding Dental Services Inextricably Linked to Treatment for Head and Neck Cancer

In the CY 2023 PFS final rule, we finalized for CY 2024 that payment under Medicare Parts A and B can be made for an oral or dental examination as part of a comprehensive workup in either the inpatient or outpatient setting, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to and contemporaneously with treatments (radiation, chemotherapy, and surgery) for head and neck cancer (87 FR 69671, 69677, and 69681–69682). We note that we stated the policy in some instances

[82] American Association of Oral and Maxillofacial Surgeons. (2022). Medication-related osteonecrosis of the Jawn-2022 update (position paper). Available at: *https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf.*

[83] American Association of Oral and Maxillofacial Surgeons. (2022). Medication-related osteonecrosis of the Jawn-2022 update (position paper). Available at: *https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf.*

[84] Yarom N, Shapiro CL, Peterson DE, et al. Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270–90. doi: *https://dx.doi.org/10.1200/JCO.19.01186.* PMID: 31329513.

without explicitly including both ''prior to'' and ''contemporaneously with.'' (87 FR 69669, 69681, 69682, and 69687.)

We also indicated that we wanted to continue to consider various aspects of our finalized policy and that we anticipated additional clarifying rulemaking on this final policy for CY 2024. In the CY 2023 PFS final rule we stated that we wanted to examine the clinical data and consider whether greater specificity may be needed to describe the medical services involved in this type of treatment. We stated that we were cognizant of concerns that, absent clear guidelines and definitions, beneficiaries, practitioners, and MACs may need additional information prior to providing payment under Medicare Parts A and B, and without it could lead to inconsistent application of the policy. In particular, we stated that it is important to determine whether any additional guidance is necessary to identify conditions considered ''head and neck cancer'' and qualifying covered medical services considered within the treatments for these cancers beyond just radiation (with or without chemotherapy).

Upon further study, as pointed out by one submitter, we understand that the term ''head and neck cancer'' encompasses a multitude of pathologies that often require multi-modality therapies including radiation, chemotherapy and surgery. This submitter noted that approximately 80 percent of head and neck cancer patients will receive radiation therapy at least once during the course of their disease. While the majority of head and neck cancers are squamous cell carcinomas that originate from the mucosa of the oral cavity, pharynx or larynx, they may also arise from the salivary glands, the nasal cavities and the paranasal sinuses. They can be locally advanced, regionally metastatic to the cervical nodes and can spread to distant sites such as the lungs and liver. According to the submitter, regardless of origin, the clinical diagnostic and therapeutic approaches for head and neck cancers are fundamentally similar, and treatment modalities often result in both acute and chronic oral toxicities.

If unaddressed, existing oral or dental infection may compromise the delivery of the appropriate modalities of care (radiation, chemotherapy, surgery). The standard of care is to address and eliminate oral and dental infections prior to the treatment of some (or many) head and neck cancers. Additionally, as discussed in section II.K.2.a of this proposed rule, the complications caused by treatment-induced vulnerabilities, which may include infection and osteoradionecrosis, can prevent the ability to proceed with the primary, covered medical service (that is, can lead to delays in treatment and/or cause inability of the patient to complete the course of treatment, thereby potentially reducing effectiveness of the therapy); and the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

As discussed in the CY 2023 final rule, we believe that addressing any oral or dental infection prior to the initiation of treatment serves to minimize the potential development of the treatment-induced complications. Moreover, we believe that these treatment-induced complications can occur as a result of and during multiple rounds of treatment.

Therefore, we are proposing to clarify that Medicare Parts A and B payment may be made for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting, as well as for the medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to the initiation of, or during, treatments for head and neck cancer, whether primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment.

In summary, we are proposing to amend our regulation at § 411.15(i)(3)(i)(A) to allow for payment under Medicare Parts A and Part B for:

(1) Dental or oral examination in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer.

We note that in the CY 2023 PFS final rule (87 FR 70225) and now codified in our regulation at § 411.15(i)(3)(i), we finalized that for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service, payment may be made under Medicare Parts A and B for services when furnished in either the inpatient or outpatient setting; therefore, we proposed that these provisions would apply to the proposed amendments to regulation at § 411.15(i)(3)(i) to allow for payment under Medicare Parts A and Part B in either the inpatient or outpatient setting. We further propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as described in our regulation at § 411.15(i)(3)(ii). If finalized, we anticipate making conforming changes to the Medicare Benefit Policy Manual (IOM Pub. 100–02) to reflect the final changes or clarifications. We seek comments on all aspects of these proposals.

3. Request for Information on Dental Services Integral to Covered Cardiac Interventions

In the CY 2023 PFS final rule, we finalized a policy to permit payment for dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered cardiac valve replacement or valvuloplasty procedures; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the cardiac valve replacement or valvuloplasty procedure (87 FR 69675).

We recognized that, without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to a cardiac valve replacement or valvuloplasty procedure, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves and the surrounding cardiac muscle tissues involved with the surgical site and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient (87 FR 69667).[85] Specifically, we noted that the replaced valve is also at risk of being a seeding source for future endocarditis. Endocarditis can carry a high risk of mortality for these patients, and eliminating an infection prior to or contemporaneously with the procedure would be important for preventing future endocarditis related to the new valve (87 FR 69678).

We also concluded that an oral or dental infection could present a substantial risk to the success of organ transplants, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present. We stated

[85] Knox, K.W., & Hunter, N. (1991). The role of oral bacteria in the pathogenesis of infective endocarditis. Australian dental journal, 36(4), 286–292. *https://doi.org/10.1111/j.1834–7819.1991.tb00724.x.*

that we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to these other covered medical services (89 FR 69667).

We encouraged the public to use the public submission process finalized in the CY 2023 PFS final rule to identify additional clinical scenarios and related medical evidence to support an inextricable link between specified dental services and other covered medical services.

Through the submission process, an interested party has encouraged CMS to consider extending Medicare payment to include dental services to eliminate infection prior to all cardiovascular procedures, as the mitigation of risks of perioperative and postoperative infection and complications is critical to ensure optimal surgical outcomes for all patients requiring invasive and/or interventional cardiac procedures. This submission noted that the current standard of care does not conclusively require dental evaluation, diagnosis, or treatment services prior to certain cardiac procedures, perhaps in part because such cardiac procedures are often performed on a more urgent or emergent basis where there is not an opportunity to consider the possible presence of dental infection. Moreover, the submission noted that much of the scientific literature is inconclusive as to whether pre-operative dental treatments impact postoperative surgical outcomes in cardiovascular surgery, including cardiac valve procedures.[86] A systematic literature review by Cotti *et al.* found that, based upon expert opinion, there is general agreement on the need for screening and treatment of oral/dental infections in patients who are to undergo cardiac surgery (although no standardized clinical guidelines or protocols exist to outline the screening process, in terms of either dental treatment options and/or timing of such procedures in relation to the planned cardiac intervention).[87] The authors convened an expert panel from six Italian scientific societies (including cardiologists, cardiac surgeons, and dental specialists) to establish a consensus on early screening and resolution of dental or periodontal infections prior to cardiac surgery, that they intended would result in a standardized protocol for evaluating oral infections and dental treatments for cardiac patients to be used in the interventional preparation phase by both dental and cardiac teams.[88] The authors noted, however, the lack of scientific evidence on the risk-to-benefit ratio for perioperative dental treatment in patients undergoing cardiovascular surgery.

We believe, after further review of current medical practice, through consultations with interested parties (including commenters on last year's final rule and those commenting on current topics) and our medical officers, and through evidence submitted through the public submission process we established in the CY 2023 PFS final rule, that there may be additional circumstances that are clinically similar to examples we codified in our regulation at § 411.15(i)(3)(i) where Medicare payment for dental services could be made under other clinical circumstances where the dental services are inextricably linked to a covered cardiac medical service(s).

To gain further understanding of any potential relationship between dental services and specific covered cardiac medical services, we again partnered with researchers at the AHRQ to review available clinical evidence regarding the relationship between dental services and covered cardiac medical services, including implantation of ventricular assist devices, artificial pacemakers, implantable defibrillators, synthetic vascular grafts and patches, and coronary and vascular stents. This AHRQ report[89] is available at *https://effectivehealthcare.ahrq.gov/products/implantable-cardiovascular-devices/rapid-review.*

As stated in their report, the available evidence does not permit conclusions regarding the effect of pre-treatment dental care for preventing downstream infections related to any of these devices. They noted that professional society guidelines endorse the provision of patient education on routine oral hygiene practices but have not recommended other pre-treatment dental care prior to insertion of these devices. They also noted that professional society guidelines recommend ongoing routine dental examinations for some patients treated with cardiovascular devices.

Nonetheless we seek comment to identify additional cardiac interventions (that is, specific medical services) where the risk of infection posed to beneficiaries is similar to that associated with cardiac valve replacement or valvuloplasty. We note that, in order to consider whether certain dental services are inextricably linked to the clinical success of other covered medical services, we need to identify specific medical services for which there is clinical evidence that certain dental services are so integral to the clinical success that they are inextricably linked to other covered service(s). We encourage interested parties to use the public submission process to submit recommendations and relevant clinical evidence for establishing this connection. Above, in section II.K.1.c. of this proposed rule, we have described the various types of documentation to support recommendations through this process. We are considering, and seek comment on, whether the following cardiac interventions are examples of specific medical services for which dental services are inextricably linked to clinical success: implantation of electronic devices in the heart, such as pacemakers, cardioverter defibrillators, and monitors. We are also considering, and seek comment on, whether the following procedures would be considered examples of specific medical services for which dental services are inextricably linked to their clinical success: the placement of intracardiac or intravascular foreign material, such as a stent or for hemodialysis, or for a vascular access graft, whereas you would not proceed with the medical service without having first completed a dental evaluation and/or treatment as determined necessary. We seek comment on whether preoperative and perioperative dental services are inextricably linked to any other covered cardiac interventions as supported by clinical evidence.

[86] Lockhart, P.B., DeLong, H.R., Lipman, R.D., Estrich, C.G., Araujo, M.W.B. and Carrasco-Labra, A. (2019). Effect of dental treatment before cardiac valve surgery: Systematic review and meta-analysis. Journal of the American Dental Association,150(9). 739–747. *https://doi.org/10.1016/j.adaj.2019.04.024.*

[87] Cotti, E., Cairo, F., Bassareo, P.P., Fonzar, F., Venturi, M., Landi, L., Parolari, A., Franco, V., Fabiani, C., Barili, F., Di Lenarda, A., Gulizia, M., Borzi, M., Campus, G., Musumeci, F., and Mercuro, G. (2019). Perioperative dental screening and treatment in patients undergoing cardiothoracic surgery and interventional cardiovascular procedures. A consensus report based on RAND/UCLA methodology. International Endodontic Journal,53. 186–199. *https://doi.org/10.1111/iej.13166.*

[88] *Ibid.*

[89] Hickam DH, Gordon CJ, Armstrong CE, Paynter R. The Efficacy of Dental Services for Reducing Adverse Events in Those Undergoing Insertion of Implantable Cardiovascular Devices. Rapid Response. (Prepared by the Scientific Resource Center under Contract No. 75Q80122C00002.) AHRQ Publication No. 23–EHC020. Rockville, MD: Agency for Healthcare Research and Quality; June 2023. DOI: *https://doi.org/AHRQEPCRAPIDDENTALCARDIO.*

4. Request for Comment on Dental Services Integral to Specific Covered Services To Treat Sickle Cell Disease (SCD) and Hemophilia

Interested parties using the public submission process we finalized in the CY 2023 PFS final rule urged us to propose to provide that payment can be made for dental services for individuals living with SCD and hemophilia.

These submissions provided information and references supporting prevention of dental infection among individuals with SCD to reduce need for more extensive procedures that may result in bleeding complications and require hospitalization. They also provided information detailing increased dental caries and periodontal disease in people with SCD,[90] many of whom lose a number of teeth, which greatly limits nutrition, general well-being, and overall quality of life.

We seek comment on whether certain dental services are inextricably linked to other covered services used in the treatment of SCD, such as, but not limited to, hydroxyurea therapy. We seek comment identifying such covered services for SCD and whether an inextricable link is supported by clinical evidence as described in section II.K.1.c. of this proposed rule.

Interested parties also urged us to propose a policy to permit payment for dental services for individuals living with hemophilia. They noted that periodic dental care reduces the risks of dental complications requiring haemostatic therapy (such as tooth extractions that may require clotting factor treatment) or oral surgeries requiring clotting factor replacement therapy.[91] [92] [93]

We note that many submitters stated that good dental and oral health benefits a patient's overall health generally. Several commenters on the CY 2023 PFS proposed rule also expressed that good oral hygiene, along with routine dental services, contributes to better outcomes for patients. We recognized in the CY 2023 PFS final rule in response to those comments that there is a great deal of evidence suggesting that dental health is generally an important component of overall health; however, we are interested in comments on whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services such that they are not subject to the statutory preclusion on Medicare payment for dental services under section 1862(a)(12) of the Act.

We seek comment on whether certain dental services are inextricably linked to certain other covered services for hemophilia, supported by clinical evidence as described in section II.K.1.c., above. We seek comment identifying such covered services for the treatment of hemophilia. We also seek comment specifically on whether dental services such as prophylaxis are a standard of care in the management of hemophilia.

5. Request for Comment Regarding Dental Services Possibly Inextricably Linked to Other Medicare-Covered Services

Commenters, submitters, and other interested parties have urged us to consider the importance of access to oral health care for people with chronic auto-immune conditions, and other chronic disease conditions, such as, but not limited to, diabetes. We understand and appreciate the interest in such requests. Because the Medicare statute generally prohibits payment for dental services payment may only be made when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services. We urge interested parties to consider the circumstances under which dental services are inextricably linked to specific covered services (not diagnoses) used to treat patients with auto-immune conditions or other chronic conditions, supported by clinical evidence as described in section II.K.1.c. of this proposed rule.

We have encouraged interested parties who believe certain dental services are inextricably linked to certain covered services to use our public submission process to provide information on these clinical scenarios, supported by clinical evidence or other documentation, as discussed in section II.K.1.c. of this proposed rule, such as that it would be the standard of care to not proceed with the medical service without having completed the dental service. Commenters are welcome to submit additional information regarding clinical scenarios presented in the CY 2023 PFS rulemaking discussions, which we are not proposing for the CY 2024, such as dental services involved with the treatment of chronic conditions such as, but not limited to, diabetes (87 FR 69686). As summarized above in section II.K.1.c. of this proposed rule, through the public submission process we finalized in the CY 2023 PFS final rule, interested parties should submit medical evidence to support an inextricable link between certain dental services and covered services by providing any of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services.

As discussed above in section II.K.1.c. of this proposed rule, in order to consider whether certain dental services are inextricably linked to the clinical success of other covered services, we need to identify specific medical services for which there is medical evidence that certain dental services are so integral to the clinical success that they are inextricably linked to the covered service. The medical evidence should support that in the case of surgery, the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure. Medical evidence should be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the primary medical procedure such that the dental services are inextricably linked to, and substantially related and integral to, the

[90] Kakkar M, Holderle K, ShethM, Arany S, Schiff L, Planerova A. Orofacial Manifestation and Dental Management of Sickle Cell Disease: A Scoping Review. Anemia. 2021 Oct 22; 2021:5556708. Doi: 10.1155/2021/5556708. PMID: 34721900; PMCID: PMC8556080.

[91] Raso S, Napolitano M, Sirocchi D, Siragusa S, Hermans C. The important impact of dental care on haemostatic treatment burden in patients with mild haemophilia. Haemophilia. 2022 Nov;28(6):996–999. doi: 10.1111/hae.14626. Epub 2022 Jul 25. PMID: 35879819.

[92] Srivastava A, Santagostino E, Dougall A, Kitchen S, Sutherland M, Pipe SW, Carcao M, Mahlangu J, Ragni MV, Windyga J, Llinás A, Goddard NJ, Mohan R, Poonnoose PM, Feldman BM, Lewis SZ, van den Berg HM, Pierce GF; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1–158. doi: 10.1111/hae.14046. Epub 2020 Aug 3. Erratum in: Haemophilia. 2021 Jul;27(4):699. PMID: 32744769.

[93] Peisker A, Raschke GF, Schultze-Mosgau S. Management of dental extraction in patients with Haemophilia A and B: a report of 58 extractions. Med Oral Patol Oral Cir Bucal. 2014 Jan 1;19(1):e55–60. doi: 10.4317/medoral.19191. PMID: 24121912; PMCID: PMC3909433.

clinical success of the covered services. Medical evidence should support that the dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient), or, medical evidence should demonstrate that the standard of care would be to not proceed with the covered medical procedure until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

6. Request for Information on Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services

We continue to consider improvements to our payment policies for dental services as finalized in the CY 2023 PFS final rule (87 FR 69663 through 69688). As such, we are interested in receiving comments from interested parties on ways to best continue to implement these policies. Additionally, given comments and questions we have received from interested parties through rulemaking and the public submission process, we want to provide further clarity on the policies we finalized in the CY 2023 PFS final rule. Therefore, we are requesting comments on several policies related to implementation of policies for dental services for which Medicare payment can be made.

In the CY 2023 PFS final rule, we clarified and codified our policy on payment for dental services and added in § 411.15(i)(3)(i) of our regulation examples of circumstances where payment can be made for certain dental services, including a dental exam and services to diagnose and eliminate an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures (87 FR 69664 through 69667).

We provided as examples of dental services that could be furnished to eradicate infection services such as, but not limited to, diagnostic services, evaluations and exams (for example, CDT codes payable with D0120, D0140 or D0150), extractions (for example, CDT codes payable with D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as filling procedures—for example, CDT codes payable with D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planing—for example, CDT codes payable with D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT codes payable with D3000–3999). However, we continue to believe that additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source. Therefore, we reiterate that such additional services would not be inextricably linked to the specific covered services. As such, no Medicare payment would be made for the additional services that are not immediately necessary to eliminate or eradicate the infection. We further clarify that we did not in CY 2023 nor are we proposing in CY 2024 to adjust any payment policy for services involving the preparation for, or placement of dentures, and maintain that these services are not payable under Medicare Parts A and B. We also reiterate our policy, as finalized in the CY 2023 PFS final rule, that Medicare could make payment for dental services occurring over multiple visits, as clinically appropriate. We refer readers to 87 FR 69678 for a more full description of this policy.

We continue to recognize that many Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan, another private insurance plan offering commercial dental coverage, or for those individuals dually eligible for Medicare and Medicaid, through a state Medicaid program. As a result, we seek comment on the coordination of multiple dental benefits that Medicare beneficiaries may have, if and how other plans currently cover and pay for dental services, and what type of guidance CMS should provide about the dental payment policies we have established and their relationship to other separate or supplemental dental coverages. We also seek comment on approaches utilized by other plans to mitigate issues with third party payment, including when Medicare is secondary payer and when coordinating with state Medicaid programs. In addition, we note there is an informal practice where dental professionals may submit a dental claim to Medicare for the purposes of producing a denial so that Medicaid or another third-party payer can make primary payment. Given the complexity of dental professionals submitting claims for purposes of denial, we seek comment on the impact of third-party payers, including state Medicaid programs, requiring a Medicare denial for adjudication of primary payment for dental services that are not inextricably linked to another specific covered service. In these cases where the dental services are not inextricably linked to another specific covered service, dental professionals must include the appropriate HCPCS modifier on the respective dental claim form, which serves as a certification that the professionals believe that Medicare should not pay the claim. We also seek comment regarding an informal process on claims denials for the purposes of supporting payment by other payers is currently achieved in practice when using the dental claim form 837d. We note that the submission of a claim without one or more of the HCPCS modifier(s) meant to produce a denial shows belief by the enrolled billing practitioner that Medicare, not another payer, should be the primary payer in accordance with all applicable payment policies. As such, submission of a claim for dental services without such a modifier would mean that the billing practitioner believes the dental service is inextricably linked to another Medicare-covered service, or that payment for the service is otherwise permitted under our regulation at § 411.15(i). We seek comment on the practices of other payers related to submission of claims in order to generate a denial and how these practices impact claim submission and claim adjudication with third party payers, including state Medicaid programs. Additionally, we are seeking comment on types of guidance, such as best practices or criteria, that are needed for purposes of coordinating payment for dental services under the policies specified in the rule.

As described in the CY 2023 PFS final rule (87 FR 69663 through 69688), Medicare payment under Parts A and B may be made for dental services that are inextricably linked to the covered primary service. We believe the dental and covered services would most often be furnished by different professionals, and that in order for the dental services to be inextricably linked to the covered services such that Medicare payment can be made, there must be coordination between these professionals. This coordination should occur between the practitioners furnishing the dental and covered services regardless of whether both individuals are affiliated with or employed by the same entity. This coordination can occur in various forms such as, but not limited to, a referral or exchange of information between the practitioners furnishing the dental and covered services. Additionally, any

evidence of coordination between the professionals furnishing the primary medical service and dental services should be documented. If there is no evidence to support exchange of information, or integration, between the professionals furnishing the primary medical service and the dental services, then there would not be an inextricable link between the dental and other covered services within the meaning of our regulation at § 411.15(i)(3). As such, Medicare payment for the dental services would be excluded under section 1862(a)(12) of the statute (though payment for the dental services might be available through supplemental health or dental coverage). Additionally, we are seeking information regarding the potential impact of these payment policies in settings other than inpatient and outpatient facilities, such as federally qualified health centers, rural health clinics, etc. We understand that some Medicare beneficiaries may access dental services in these settings and seek to understand what, if any, impact may potentially occur within the context of this payment policy.

As stated in the CY 2023 PFS final rule, we note that, to be eligible to bill and receive direct payment for professional services under Medicare Part B, a dentist must be enrolled in Medicare and meet all other requirements for billing under the PFS. Alternatively, a dentist not enrolled in Medicare could perform services incident to the professional services of a Medicare enrolled physician or other practitioner. In that case, the services would need to meet the requirements for incident to services under § 410.26, including the appropriate level of supervision, and payment would be made to the enrolled physician or practitioner who would bill for the services (87 FR 69673). In the CY 2023 PFS final rule (87 FR 69687), we finalized that we would continue to contractor price the dental services for which payment is made under § 411.15(i)(3). We will maintain this policy and continue to contractor price the dental services for which payment is made under § 411.15(i)(3) for CY 2024. Additionally, in the CY 2023 PFS final rule, we agreed with the suggestions made by commenters that there may be publicly available data sources that could aid MACs in determining these payment rates in order to account for geographic variation. Recognizing that dental offices may range in the services that they provide, from simple office visits to complex surgical procedures, dental services will continue to be contractor priced. We are seeking comment on what specific information could help inform appropriate payment for these dental services (87 FR 69679).

In the CY 2023 PFS final rule (87 FR 69682), we stated that we would update our payment files, so that these dental services could be billed appropriately under the applicable payment system for services furnished in either the inpatient or outpatient setting. We have revised the HCPCS and PFS payment and coding files to include payment indicators for Current Dental Terminology (CDT) codes, such as bilateralism, multiple procedures, and other indicators that are included in the PFS Relative Value (RVU) files (posted at our website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files*) for CDT codes. We seek comment on whether payment indicators as outlined in the PFS RVU files appropriately align with existing dental billing and coding conventions, or whether edits are necessary. Medical and dental providers should bill using CDT or Current Procedure Terminology (CPT) codes where applicable, and for claims submissions during CY 2023, should submit claims using the professional or institutional claim forms, as appropriate. Although we propose to continue contractor pricing services billed using CDT codes, we are soliciting comment on whether the current payment indicators included for these CDT codes follow existing dental billing conventions, for example, for payment adjustment for multiple procedures, and whether there is a need for additional guidance regarding the submission of claims for services for which payment is permitted under the regulation at § 411.15(i)(3). In the CY 2023 PFS final rule (87 FR 69679), we acknowledged the need to address and clarify certain operational issues, and we are continuing to work to address these operational issues, including efforts to adopt the dental claim form. These efforts include continuing to work with our MACs and encouraging continued feedback from interested parties to help identify concerns or questions regarding the submission and processing of dental claims.

Finally, in order to promote the correct coding and processing of Medicare claims, dentists who practice general or specialized dentistry currently self-designate their specialty under two specialty codes, specialty 19 (oral surgery—dentists only) or specialty 85 (maxillofacial surgery). We seek comment on whether additional specialty codes should be considered for use in Medicare, and if so, what are the other specific specialties that should be included. We also seek comment on whether these specialty codes may impact the coordination of benefits with a third-party payer. Finally, we recognize that issues could occur related to coordination of benefits for dual eligible beneficiaries, for example beneficiaries with hemophilia, and we seek comment on how to best coordinate a potential payment policy in this area with respect to state Medicaid plans or private insurance. We also seek comment on other coordination of benefits issues, or implementation topics that would be helpful for CMS to address in relation to continuing to implement these PFS payment policies.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Provisions From the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B (§§ 410.152, 414.902, 414.904, 489.30)

Drugs and biologicals (for the purposes of the discussion in this section III.A., ''drugs'') payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(n) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment amounts for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on.

The Inflation Reduction Act (Pub. L. 117–169, August 16, 2022) (hereinafter referred to as ''IRA'') contains several provisions that affect payment limits or beneficiary out-of-pocket costs for certain drugs payable under Part B. Among those provisions, two affect payment limits for biosimilar biological products (hereinafter referred to as ''biosimilars''):

- Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period when ASP data is not available. We are proposing to codify this provision in regulation.
- Section 11403 of the IRA makes changes to the payment limit for certain

biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years. We implemented section 11403 of the IRA under program instruction,[94] [95] as permitted under section 1847A(c)(5)(C) of the Act. We are now proposing conforming changes to regulatory text to reflect these provisions.

In addition, two provisions (among others in the IRA) make statutory changes that affect beneficiary out-of-pocket costs for certain drugs payable under Medicare Part B:

- Section 11101 of the IRA requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. We issued initial guidance implementing this provision, as permitted under section 1847A(c)(5)(C) of the Act, on February 9, 2023.[96] We are proposing conforming changes to regulatory text.
- Section 11407 of the IRA provides that for insulin furnished through an item of DME on or after July 1, 2023, the deductible is waived and coinsurance is limited to $35 for a month's supply of insulin furnished through a covered item of DME. We have implemented this provision under program instruction for 2023, as permitted under section 11407(c) of the IRA.[97] We are now proposing to codify this provision in a manner that is consistent with the program instruction for 2023.

a. Payment for Drugs Under Medicare Part B During an Initial Period

Section 1847A of the Act provides for certain circumstances in which the payment limit of a drug is based on its wholesale acquisition cost (WAC). For a single source drug or biological (as defined in section 1847A(c)(6)(D) of the Act), the Medicare payment could have a WAC-based payment determined under the methodology specified in section 1847A(b)(4) of the Act and described at § 414.904(d)(1), which requires that payment limits for such drugs are determined using the lesser of ASP plus 6 percent or WAC plus 6 percent. Typically, the ASP-based payment limit is the lesser of the two. Under section 1847A(c) of the Act, payments for new drugs during an initial period for which ASP data is not sufficiently available are based on WAC or the Medicare Part B drug payment methodology in effect on November 1, 2003. Historically, WAC-based payment under section 1847A(c)(4) of the Act was up to 106 percent of WAC, but in the CY 2019 PFS final rule (83 FR 59661 through 59666), we adopted a policy of paying up to 103 percent of WAC in this instance. Subsequently, section 6 of the Sustaining Excellence in Medicaid Act of 2019 (Pub. L. 116–39, enacted August 6, 2019), amended section 1847A(c)(4) of the Act to specify, effective January 1, 2019, a payment limit not to exceed 103 percent of the WAC or based on the Part B drug payment methodology in effect on November 1, 2003 during an initial period when ASP data is not sufficiently available. There were no regulatory changes at that time. Therefore, we are proposing to amend § 414.904(e)(4) to reflect this statutory change.

More recently, section 11402 of the IRA amended section 1847A(c)(4) of the Act by adding subparagraph (B), which limits the payment amount for biosimilars during the initial period described in section 1847A(c)(4)(A) of the Act. The provision requires that for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not sufficiently available, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological.

We propose to codify these changes to section 1847A(c)(4) of the Act at § 414.904. Specifically, we are proposing to revise paragraph (e)(4) at § 414.904 by adding paragraphs (e)(4)(i)(A) and (B) to conform the regulatory text for WAC-based payment limits before January 1, 2019 and for such payment limits on or after January 1, 2019 with the requirements established in section 6 of the Sustaining Excellence in Medicaid Act of 2019. We are also proposing to add paragraphs (A) and (B) to § 414.904(e)(4)(ii) to codify the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period as required by section 1847A(c)(4)(B) of the Act.

b. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products

Consistent with section 1847A(b)(8) of the Act, Medicare Part B payment limit for a biosimilar is its ASP plus 6 percent of the reference biological product. In the CY 2016 PFS final rule (80 FR 71096 through 71101), we clarified that the payment limit for a biosimilar biological product is based on the ASP of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code and amended § 414.904(j) to reflect this policy. In the CY 2018 PFS final rule (82 FR 53182 through 53186), we finalized a policy to separately assign individual biosimilar biological products to separate billing and payment codes and pay for biosimilar biological products accordingly. However, we did not change the regulation text at § 414.904(j) at that time.

Section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment limit increase for qualifying biosimilar biological products furnished during the applicable 5-year period. Section 1847A(b)(8)(B)(iii) of the Act defines ''qualifying biosimilar biological product'' (hereinafter referred to as ''qualifying biosimilars'') as a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an ASP (as described in section 1847A(b)(8)(A)(i) of the Act) less than the ASP of the reference biological for a calendar quarter during the applicable 5-year period. Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference biological's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022 as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022 and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment.[98]

[94] *https://www.cms.gov/files/document/r11496cp.pdf.*

[95] *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

[96] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[97] *https://www.congress.gov/bill/117th-congress/house-bill/5376/text.*

[98] In accordance with these provisions, the ASP Drug Pricing File reflects the temporary increased payment limit for qualifying biosimilars beginning with the October 2022 file available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

In this proposed rule, we propose to add definitions of ''applicable 5-year period'' and ''qualifying biosimilar biological product'' at § 414.902 to reflect the definitions in statute, and we propose to make conforming changes to regulatory text to reflect the requirements mandated under section 1847A(b)(8)(B) of the Act for the temporary payment limit increase for qualifying biosimilar biological products at § 414.904 (j) by adding paragraphs (j)(1) and (2).

c. Inflation-Adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs

Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA are currently being implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we issued final guidance for the computation of inflation-adjusted beneficiary coinsurance under section 1874A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act on February 9, 2023.[99] [100] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare.*

Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the amount specified in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug. In this proposed rule, we propose to codify the coinsurance amount for Part B rebatable drugs as required by section 1847A(i)(5) of the Act in § 489.30, specifically by adding a new paragraph (b)(6).

Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the inflation-adjusted payment amount of a Part B rebatable drug exceeds the payment amount described in section 1847A(i)(3)(A)(ii)(I) (or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B), the Part B payment will, subject to the deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. In this proposed rule, we propose to codify the Medicare payment for Part B rebatable drugs in § 410.152, specifically by adding new paragraph (m).

d. Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment

Drugs furnished through a covered item of DME are covered under Medicare Part B as provided in sections 1861(n) and (s)(6) of the Act. Insulin administered through covered DME, such as a durable insulin pump, is covered under this benefit. As required by section 1842(o)(1)(C) and (D) of the Act, effective January 1, 2017, infusion drugs furnished through DME, including insulin, are paid under section 1847A of the Act (see 82 FR 53180 through 53181), which is typically ASP plus 6 percent. Prior to July 1, 2023, beneficiaries are responsible for coinsurance of 20 percent of the payment amount of such insulin, subject to the Part B deductible.

Section 11407 of the IRA made three changes to the manner in which beneficiaries pay for insulin furnished through covered DME. First, section 11407(a) of the IRA amended section 1833(b) of the Act to waive the Part B deductible for insulin furnished through covered DME on or after July 1, 2023. Second, section 11407(b)(2) of the IRA amended section 1833(a) of the Act to establish a limit of $35 on the beneficiary coinsurance amount for a month's supply of such insulin furnished on or after July 1, 2023. This statutory change means that the beneficiary coinsurance responsibility, which is limited to $35 for a month's supply of insulin, could equal less than 20 percent if the Part B payment amount of a month's supply of insulin is greater than $175. Third, section 11407(b)(2) of the IRA also added a new sentence to section 1833(a) of the Act to require the Secretary to increase to the Medicare Part B payment to above 80 percent in the case the coinsurance amount for insulin furnished through covered DME equals less than 20 percent of the payment amount to pay for the full difference between the payment amount and coinsurance. The adjustment specified in paragraph (b)(2) ensures the supplier is not responsible for the reduction in the beneficiary coinsurance amount.

The above provisions were implemented through program instruction,[101] as required by section 11407(c) of the IRA, for CY 2023. Section 80 in Chapter 17 and section 140 in Chapter 20 of the Medicare Claims Processing Manual will be updated to reflect these changes, effective July 1, 2023. To operationalize this provision, the $35 coinsurance limit applies to the duration of the calendar month in which the date of service occurs. As stated in the section 110.5, Chapter 15 of the Medicare Benefit Policy Manual,[102] the date of service on the claim must be the date that the beneficiary or authorized representative receives the insulin or, for mail order, the date the insulin is shipped. A new $35 coinsurance limit for a month's supply applies to each calendar month. It follows that, as stated in the program instruction, when a 3-month supply (that is, the amount of such insulin that is required for treatment for up to 3 calendar months) is billed for insulin furnished through covered DME, that a coinsurance limit of $105 would apply for that 3-calendar month period ($35 coinsurance limit for each month's supply of insulin). The program instruction also states that the Medicare Administrative Contractors (MACs) will ensure that coinsurance does not exceed $35 for a 1-month supply or $105 for a 3-month supply for claims billing insulin administered through covered DME.

[99] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[100] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

[101] *https://www.cms.gov/files/document/r11917cp.pdf.*

[102] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/bp102c15.pdf.*

Here, we propose to codify these elements (that are currently in program instruction) for CY 2024 and future years in regulation text, because section 11407(c) of the IRA states that only implementation for CY 2023 may be through program instruction or other forms of guidance. Specifically, we propose to codify the new statutory monthly coinsurance limits of $35 for a 1-month supply and $105 for a 3-month supply at § 489.30 by adding paragraph (b)(7) and the adjustment to the provider payment at § 410.152 by adding paragraph (n). In addition, we propose to codify at § 489.30 that the $35 coinsurance limit for a month's supply of insulin furnished through covered DME will apply to the duration of the calendar month in which the date of service (or services) occurs. In other words, the $35 coinsurance limit will apply for a month's supply of insulin each calendar month. Similarly, we propose to codify that the $105 coinsurance limit for 3 months' supply of insulin furnished through covered DME will apply to the duration of the calendar month in which the date of service (or services) occurs and the 2 following calendar months

2. Request for Information (RFI): Drugs and Biologicals Which Are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

Section 1861(s)(2)(A) of the Act allows Medicare to pay for services and supplies, including drugs and biologicals (hereafter, drugs) that are not usually self-administered by the patient, which are furnished as ''incident to'' a physician's professional service. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) (Pub. L. 106–554, December 21, 2000) amended the above-referenced sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, which formerly referred to drugs ''which cannot be self-administered,'' to read, ''which are not usually self-administered.'' Drugs that are ''usually self-administered'' are thus statutorily excluded from coverage and payment under Part B under the ''incident to'' benefit.

We have provided definitions and other guidance for MACs regarding determinations on drugs that are ''not usually self-administered by the patient'' in Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual. Chapter 15 also describes the evidentiary criteria that MACs should use in determining whether a drug is usually self-administered. The guidance directs MACs to publish a description of the process they use to make that determination, and to publish a list of the drugs that are subject to the self-administered exclusion on their website. The guidance also requires that this list include the data and rationale that led to the determinations. This list is referred to as the ''self-administered drug (SAD) list,'' and each MAC maintains their own version of the list, which is applicable to that MAC's area of jurisdiction. While the lists are often similar between MACs, they are not identical. Drugs that are put on a SAD list are excluded from Part B coverage, but in those situations, they are almost always covered by Medicare Part D prescription drug coverage. For several years, interested parties have requested that we update and clarify this SAD list guidance. These parties believe that the current guidance may not adequately address circumstances posed by newly approved drugs.

In a similar vein, we have received concerns from interested parties that non-chemotherapeutic complex drug administration payment has become increasingly inadequate due to existing coding and Medicare billing guidelines that do not accurately reflect the resources used to furnish these infusion services. Interested parties have asserted that these infusion services are similar to complex and clinically intensive Chemotherapy and Other Highly Complex Biological Agent Administration (''Chemotherapy Administration'') services that are billed using CPT code series 96401–96549, as opposed to Therapeutic, Prophylactic, and Diagnostic Injections and Infusion services billed using CPT code series 96360–96379. We note that we discuss our policies for these services in Pub. 100–04 Medicare Claims Processing Manual, Chapter 12, Section 30.5D.

We are soliciting comments on the above two policy areas, since they both involve Part B drug payment policies that have been impacted by new developments in the field. In an effort to promote coding and payment consistency and patient access to infusion services, we are seeking comment and information from interested parties regarding the relevant resources involved, as well as inputs and payment guidelines and/or considerations, that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration. We are seeking comment on whether or not we should revise our policy guidelines as discussed to better reflect how these specific infusion services are furnished and should be billed.

We are also soliciting comments regarding our policies on the exclusion of coverage for certain drugs under Part B which are usually self-administered by the patient. Specifically, we are soliciting comments regarding our policies for the following items:

- Definitions of the following terms, as referenced in this section:
  - ++ ''Administered.''
  - ++ ''Self-Administered.''
  - ++ ''Usually.''
  - ++ ''By the patient.''
- The process for determining which drugs are classified as those ''not usually self-administered by the patient.''
- The process for issuing decisions on which drugs are classified as those ''not usually self-administered by the patient,'' and the process for issuing any changes to those classifications.
- The relevant resources involved, as well as inputs and payment guidelines and/or considerations, that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration.
- Whether or not CMS should revise policy guidelines to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.

3. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect To Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (hereinafter is referred to as ''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereafter referred to as ''refundable drug''). The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter.

In the CY 2023 PFS final rule (87 FR 69710 through 69734), we adopted many policies to implement section 90004 of the Infrastructure Act. We finalized the requirement that billing providers and suppliers report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023. We also finalized the requirement that billing providers and suppliers report the JZ modifier for all

such drugs with no discarded amounts beginning no later than July 1, 2023, and we stated that we would begin claims edits for both the JW and JZ modifiers beginning October 1, 2023 (87 FR 69718 through 69719). Subsequent to the issuance of the CY 2023 PFS final rule, CMS published the JW Modifier and JZ Modifier Policy Frequently Asked Questions (FAQ) document [103] addressing the correct use of these modifiers. We adopted a definition of ''refundable single-dose container or single-use package drug'' at 42 CFR 414.902, which also specifies exclusions from this definition (87 FR 69724). These three exclusions are: radiopharmaceutical or imaging agents, certain drugs requiring filtration, and drugs approved by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months. Regarding reports to manufacturers, we specified that CMS would send reports (including information described in section 1847A(h)(1) of the Act) for each calendar quarter on an annual basis to all manufacturers of refundable drugs (87 FR 69726). We finalized the manner in which the refund amount will be calculated at § 414.940 (87 FR 69731). Regarding drugs with unique circumstances for which CMS can increase the applicable percentage otherwise applicable for determining the refund, we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69731). Lastly, we adopted a dispute resolution process through which manufacturers can challenge refund calculations, and we established enforcement provisions (including manufacturer audits, provider audits, and civil money penalties required by statute) (87 FR 69732 through 69734).

As noted in the CY 2023 PFS final rule (87 FR 69711), sections 11101 and 11102 of the Inflation Reduction Act (IRA) (Pub. L. 117–169, August 16, 2022) established new requirements under which manufacturers must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. Drug manufacturers are required to pay rebates to Medicare if prices for certain Part B drugs increase faster than the rate of inflation for quarters beginning with the first quarter of 2023; drug manufacturers are required to pay rebates to Medicare if prices for certain Part D drugs increase faster than the rate of inflation over 12-month periods, starting with the 12-month period that began October 1, 2022.

We explained that we believe implementation of the Part B and Part D inflation rebate programs established under the IRA should be considered together with the operational implications of the discarded drug refunds, because the refunds and rebates both require CMS to accept from drug manufacturers payments that must be deposited into the Federal Supplementary Medical Insurance (SMI) Trust Fund.

Therefore, to align the operation of these programs and minimize burden, we declined to finalize some aspects of the invoicing and collection of discarded drug refunds. Specifically, we declined to finalize the timing of the initial reports and which quarters' information will be included in each report. We also declined to finalize specific dates by which manufacturer refund obligations are due and those associated with the dispute resolution process, as those are scheduled in tandem with the reporting dates. Lastly, we stated our intent to address these aspects in future rulemaking.

In this proposed rule, we propose the date of the initial report to manufacturers, the date for subsequent reports, method of calculating refunds for discarded amounts in lagged claims data, method of calculating refunds when there are multiple manufacturers for a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug, which would precede proposals to increase applicable percentages in rulemaking. We also propose modification to the JW and JZ modifier policy for drugs payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug.

b. Provision of Information to Manufacturers

In the CY 2023 PFS final rule (87 FR 69724 through 69726), we discussed our proposals related to meeting the requirements under section 1847A(h)(1) of the Act related to the timing and contents of the report to manufacturers, including what types of information to include, which quarters' data we would include in the initial report, the amount of lagged claims data we would include, whether to send reports quarterly or annually, and the definition of a manufacturer. However, we explained that due to the enactment of the IRA and our efforts to align the operations of the refunds with the inflation rebate programs and minimize burden, we did not finalize certain aspects of the discarded drug refund provision. Specifically, we did not finalize the date that we would send the first report to manufacturers or which quarters' information would be included in each report.

Although we did not finalize the noted aspects related to timing, we adopted regulations at § 414.940(a)(3) providing that we will send reports to manufacturers on an annual basis and indicated in the preamble text that reports will contain discard information (described in section 1847A(h)(1)(A) of the Act) for each calendar quarter (87 FR 69724 through 69726). We also finalized that we will send reports to all manufacturers of refundable drugs. In addition, in response to commenters suggesting that we provide manufacturers an opportunity to engage with us on discard amount data in the first year of this provision's implementation, we stated that we would issue, no later than December 31, 2023, a preliminary report on estimated discarded amounts based on available claims data from the first two quarters of CY 2023.

To implement the discarded drug refund in a timely manner, we propose to issue the initial refund report to manufacturers, to include all calendar quarters for 2023, no later than December 31, 2024. (Note that this report, which we refer to as the ''initial refund report'' in this proposed rule, would be separate and distinct from the preliminary report that we intend to issue by December 31, 2023, that will include estimated discarded amounts based on available claims data for the first two quarters of CY 2023.)

With respect to subsequent annual reports, that is, reports for quarters in 2024 and thereafter, we intend to align delivery of the refund reports with the delivery of Part B and Part D inflation rebate reports to the extent practicable. As stated in the initial guidance for Part B inflation rebates,[104] inflation rebate reports will be sent on a quarterly basis, each no later than 6 months after the end of the calendar quarter as required in section 1847A(i)(1)(A) of the Act. Consistent with section 1847A(i)(1)(C) of the Act, CMS may delay reporting Part B inflation rebate information for

[103] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

[104] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

calendar quarters in CY 2023 and CY 2024 until September 30, 2025.[105]

To align these reports, we propose that, other than for the initial refund report, we will send annual refund reports for discarded drug refunds for the 4 quarters of a calendar year at or around the time we send Part B inflation rebate report for the first quarter of the following year. Thus, for example, we would send the second refund report for the calendar quarters in 2024 when we send the inflation rebate report for Q1 2025, which is required to be sent no later than September 30, 2025.

As noted in the CY 2023 PFS final rule (87 FR 69725), because providers and suppliers have a 12-month period to submit Medicare Part B claims, including claims for drugs payable under Part B, there can be a lag between the date of service when a drug is administered and when the claim is submitted and adjudicated. Therefore, there is a lag in available JW modifier data for any given date of service quarter. An evaluation of July 2010 Medicare Part B claims in the Physician/Supplier-Carrier setting showed that 91.68, 96.84, and 98.32, and 99.13 percent of claims were final at 3, 6, 9, and 12 months, respectively, following the date of service. At 24 and 48 months after the date of service, 99.83 and 100 percent of the claims, respectively, were considered to be final. Since, based on our evaluation of the 2010 claims data, a small percentage of lagged claims data from a calendar quarter likely would not be available when the quarter is first included on a report, we propose that annual reports (subsequent to the initial report) include lagged claims data (that is, true-up information) for quarters from 2 calendar years prior. In other words, we propose that each report would include information for 8 calendar quarters: 4 from the previous calendar year (hereafter, referred to as new refund quarters) and 4 from 2 calendar years prior (hereafter, referred to as updated refund quarters). We propose all reports (except the initial refund report) would include the following information for updated refund quarters to address lagged claims data:

- The updated total number of units of the billing and payment code of such drug, if any, that were discarded during such updated refund quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).
- The updated refund amount that the manufacturer is liable for with respect to such updated quarter that was not previously accounted for in the prior year's report.

For example, as proposed above, the second annual report (sent no later than September 30, 2025) would include: (1) the total number of units of the billing and payment code of such drug, if any, that were discarded during new refund quarters (all calendar quarters in 2024), (2) the refund amount that the manufacturer is liable for pursuant to section 1847A(h)(3) of the Act for all calendar quarters in 2024, (3) the updated total number of units of the billing and payment code of such drug, if any, that were discarded during the updated refund quarters (all calendar quarters in 2023), and (4) the refund amount that the manufacturer is liable for or the amount CMS owes the manufacturer pursuant to section 1847A(h)(3) of the Act for all calendar quarters in 2023 that was not accounted for in the previous year's report.

We are proposing to define ''new refund quarter'' and ''updated refund quarter'' at § 414.902 and to revise § 414.940(a)(3) to reflect the inclusion of lagged data in reports subsequent to the initial refund report. We solicit comment on these proposals. See section III.A.3.d. of this rule for the proposed calculation of refund amounts for updated refund quarters.

c. Manufacturer Provision of Refund

In the CY 2023 PFS final rule (87 FR 69726 through 69727) we adopted § 414.940(b), which requires manufacturers to pay refunds in 12-month intervals in a form and manner specified by CMS. In the CY 2023 PFS final rule (87 FR 69727), we also discussed our proposal for the timing of both the initial report and manufacturers' corresponding refund obligations. That is, we proposed to issue reports to manufacturers by October 1 and require refund obligations to be paid by December 31, except in circumstances where a dispute is pending. Regulations at § 414.940(b)(2) specify that in the case that a disputed report results in a refund amount due, that amount must be paid no later than 30 days after resolution of the dispute.

However, we declined to finalize the deadlines by which manufacturer refund obligations are due and those associated with the dispute resolution process, as those timelines correspond with the dates of the annual refund reports and, as explained above, we declined to finalize the timeline for the report in the CY 2023 PFS final rule in order to align the operation of the discarded drug refunds with the inflation rebate programs. In the CY 2023 PFS final rule (87 FR 69727), we stated our intent to revisit the process and timeline for manufacturers' provisions of refunds in future rulemaking.

As described in section III.A.3.b. of this proposed rule, we are proposing to issue the initial refund report to manufacturers no later than December 31, 2024. Accordingly, we propose to require that the refund amounts specified in the initial refund report be paid no later than February 28, 2025, except in circumstances where a report is under dispute. We believe a payment deadline that is two calendar months after the issuance of the report provides adequate time for manufacturers to review the reports and submit a dispute if needed prior to the refund payment deadline.

As noted above, we are proposing that we will issue the second annual refund report to manufacturers no later than September 30, 2025, and once annually thereafter no later than September 30 for every year thereafter. Accordingly, we are proposing to require manufacturers to pay refunds specified in each report (beginning with the second report) no later than December 31 of the year in which the report is sent, except in circumstances where a report is under dispute. In cases in which a manufacturer disputes a report, beginning with the initial refund report, any manufacturer liability determined upon the resolution of the dispute would be due by the above stated due date or 30 days following the resolution, as described in § 414.940(b)(2), whichever is later. We propose to revise § 414.940(b)(1) to reflect these dates.

d. Refund Amount

(1) Calculation of Refund Amounts for Updated Quarters

As discussed in section III.A.3.b. of this proposed rule, we are proposing to include information for lagged claims data in all reports other than the initial report. In addition, we propose that such additional lagged JW modifier data, if any, will be used to calculate revisions to the manufacturer refund amount. Specifically, we propose to calculate the refund with updated data in the same manner as was finalized in the 2023 PFS final rule (87 FR 69727) and subtract the refund amount that already paid for such refundable drug for such quarter to determine the updated quarter refund amount. We propose that the refund amount owed

[105] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

by a manufacturer, with respect to a refundable drug assigned to a billing and payment code for an updated refund quarter is the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

- Exceeds the difference of:

++ An amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter; and

++ The refund amount previously paid for such refundable drug for the given quarter.

We propose that if the resulting refund calculation for an updated quarter is a negative number, then it will be netted out of the any refund owed for other updated quarters or new quarters.

We propose to revise § 414.940 by adding new paragraphs (c)(2) and (3) to reflect the above proposed method of calculation of revisions to the refund amount owed for quarters in the year that is two calendar years prior.

(2) Calculation of Refund for a Drug When There Are Multiple Manufacturers

In the CY 2023 PFS final rule (87 FR 69727 through 69731), consistent with section 1847A(h)(3) of the Act, we adopted regulations at § 414.940(c) specifying the manner in which the refund amount will be calculated with respect to a refundable drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023. The refund for which the manufacturer is liable is the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter;

- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter.

We stated we will estimate the total allowed charges during the quarter by multiplying the drug's payment amount for the quarter by the total number of units of the billing and payment code of such drug that were subject to JW modifier reporting including those for which the JZ modifier would be required if no units were discarded. As specified in section 1847A(h)(1)(C) of the Act, the total number of units of the billing and payment code of a refundable drug paid during a calendar quarter for purposes of subparagraph (A)(i) and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii) exclude such units that are packaged into the payment amount for an item or service and are not separately payable.

Because refundable drugs are single source drugs or biologicals, they typically will have one manufacturer. However, a refundable drug could have more than one manufacturer, for example, in the circumstance where a refundable drug is produced by one manufacturer, and also by one or more manufacturer(s) that is a repackager or relabeler. Multiple manufacturers of a refundable drug could also occur in the case of one or more authorized generic products that are marketed under the same FDA-approval as the original FDA applicant. In such cases, the National Drug Codes (NDCs) for the drug typically are assigned to the same billing and payment code, and each manufacturer is responsible for reporting ASP data to CMS, which includes sales volume. In the CY 2023 PFS final rule (87 FR 69724 through 69726), we stated that we would identify the manufacturer responsible for the provision of refunds by the labeler code of the refundable drug.

Therefore, there is a need to establish a method for apportioning billing units of a refundable drug sold during a calendar quarter in situations where there are multiple manufacturers of a refundable drug. When calculating the refund amount owed by manufacturers for a refundable drug that has more than one manufacturer, we propose to identify such refundable drugs using the ASP sales data reported for the calendar quarter for which a refund amount is calculated. Furthermore, we propose to apportion financial responsibility for the refund amount among each manufacturer in the following manner: by dividing the sum of the individual manufacturer's billing units sold during the refund quarter for all the manufacturer's NDCs assigned to the billing and payment code (as reported in the ASP data submissions), by the sum of all manufacturers' billing units sold during the refund quarter for all NDCs of the refundable drug assigned to the billing and payment code (as reported in the ASP data submissions).

This calculation approach is consistent with the approach for apportioning inflation rebate obligations discussed in section 50.13 of the Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments,[106] released on February 9, 2023.

We propose to apportion the discarded drug refund when there is more than one manufacturer for a refundable drug, using the proportion of billing unit sales, expressed as a percentage, attributed to each NDC (at the NDC–11 level) assigned to the billing and payment code for such refund quarter. The number of billing unit sales for each NDC would be the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC. We propose that the refund amount attributed to such NDCs for which the manufacturer is liable would be the amount equal to the estimated amount (if any) by which:

- The product of:

++ The total number of units of the billing and payment code for such drug that were discarded during such quarter;

++ The percentage of billing unit sales of the applicable code attributed to the NDC; and

++ The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter;

- Exceeds an amount equal to the product of:

++ The applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter; and

++ The percentage of billing unit sales of the applicable code attributed to the NDC.

For example, if a billing and payment code for a refundable drug includes three NDCs, each from a different manufacturer as shown below in Table 18, there were 3,000 units discarded during the refund quarter, the payment limit amount for the refundable drug was $50.00 per billing unit, the applicable percentage was 10 percent, and the estimated total allowed charges for the refundable drug during the refund quarter was $1.05 million, the proposed calculation for the refund amount owed by Manufacturer 1 would

[106] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

be as follows: (3,000)(23.81%)($50) − (21,000)(10%)(23.81%)($50) = refund amount of $10,714.50.

TABLE 18: Example of Proportion of Sales Calculation when there are Multiple Manufacturers for a Refundable Drug

NDC	Manufacturer	Refund Quarter Sales (billing units)	Proportion of Sales (percent)
12345-6789-01	Manufacturer 1	5,000	23.81%
23456-7890-01	Manufacturer 2	6,000	28.57%
34567-8901-01	Manufacturer 3	10,000	47.62%
	TOTAL:	21,000	100%

The report to manufacturers described in section 1847A(h)(1) of the Act and discussed in the previous section III.A.3.b. of this proposed rule, in the case that there are multiple manufacturers for a refundable drug, would include: (1) the total number units of the billing and payment code of such drug attributed to the manufacturer's NDC assigned to the billing and payment code of the refundable drug that were discarded during such quarter, if any; and (2) the refund amount that the manufacturer of that NDC is liable for pursuant to section 1847A(h)(3) of the Act. We propose that this method of calculation apply beginning with calendar quarters in CY 2023 included in the initial refund report, which we propose to be sent no later than December 31, 2024. We propose that this method of calculation would be done for new refund quarters and updated refund quarters.

We propose to revise § 414.940 by adding a new paragraph (c)(4) to reflect the above proposed method of calculation of the refund amount attributed to a NDC when there are multiple manufacturers.

(3) Increased Applicable Percentage for Drugs With Unique Circumstances

Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. In the CY 2023 PFS final rule (87 FR 69727 through 69731), we adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (§ 414.490(d)(1)). We have identified only one drug, Jelmyto® (mitomycin for pyelocalyceal solution), with such unique circumstances. We stated in that final rule that we recognize that there are drug products that may indeed have other unique circumstances, and that an increased applicable percentage for these products would have to be determined through future notice and comment rulemaking, as required by the statutory provision. We stated that we planned to collect additional information about drugs that may have unique circumstances along with potential increased applicable percentages that might be appropriate for such drugs, and to collect additional information about a process to identify unique circumstances based on manufacturer input. We explained that we would revisit additional increased applicable percentages for drugs that have unique circumstances, and a process to identify such circumstances, through future notice and comment rulemaking. To that end, we hosted a town hall meeting on February 1, 2023 to discuss what criteria would be appropriate to determine whether a refundable drug has unique circumstances, and whether a categorical approach (that is, unique circumstances that apply to more than one drug), drug-by-drug approach, or a hybrid of these two approaches should be used for determining drugs for which an increased applicable percentage is appropriate.

After considering input from interested parties provided at the town hall and in subsequent meetings, in this proposed rule, we are proposing a hybrid approach to determining when it is appropriate to increase the applicable percentage for a drug with unique circumstances. First, we are proposing two categorical unique circumstances along with proposed increased applicable percentages and, secondly, we are proposing an application process so manufacturers may request that CMS consider whether an increased applicable percentage would be appropriate for a particular drug in light of its unique circumstances (and if an increased applicable percentage is considered appropriate it would then be proposed in future notice-and-comment rulemaking).

As discussed in the CY 2023 PFS final rule and further discussed at the town hall, many interested parties requested CMS increase applicable percentages (defined at § 414.940(c)(3) as 10 percent, except where an increased applicable percentage is applied in paragraph (d) of that section) for drugs packaged with small vial fill amounts or low-volume products (generally, those with a fill amount less than 1 mL). These parties stated that, for certain drugs, the small volume of drug contained in the vial (as identified on the package or FDA labeling) often represents the minimum volume necessary to safely and effectively prepare and administer the prescribed dose. Certain labeled amounts that are unused and discarded include amounts remaining in the syringe hub, amounts remaining in the syringe that are not part of the prescribed dose, amounts left in the vial that cannot be removed (such as drug adhering to the side of the vial or pooling around the vial stopper), and amounts left in the vial when it contains enough drug for two administration attempts.

We agree that such drugs have unique circumstances, because certain FDA-labeled amounts on the vial or package are unused and discarded after administration of the labeled dose, and these amounts are not available to be administered. The unique circumstances described for such drugs are similar to loss of product from filtration described in section 1847A(h)(8)(B)(ii) of the Act because in both circumstances, such amounts lost are amounts that are not part of the recommended dose and are not available to be administered to the patient (one being loss due to labeled amounts remaining in the filter and the other due to labeled amounts remaining

in other areas such as the vial or syringe).

Since not all drugs with small fill volumes have certain labeled amounts that are unused and discarded, we believe more specific criteria are required to identify certain drugs with unique circumstances in this case. For example, if a drug is available as 0.8 mL in a prefilled syringe, the total volume in the presentation is small, however, the entire labeled amount in the syringe may be administered to the patient as part of a labeled dose; the unique circumstances described above only occur when the volume of the labeled dose that is withdrawn from a vial or container is very small and there is a labeled amount that is unused and discarded and not available for administration, (based on drugs currently available in the market, we have observed this to occur with doses contained within less than 0.4 mL). Therefore, we propose an increased applicable percentage for drugs with a ''low volume dose.'' We consider a low volume dose to be a dose of a drug for which the volume removed from the vial containing the labeled dose does not exceed 0.4 mL (which is about 8 drops of liquid). We propose to revise § 414.902 and define a low volume dose to be a labeled dose (based on FDA-approved labeling) that is contained within no more than 0.4 mL when removed from the vial or container. For example, if a labeled dose is 4 mg and a vial contains a suspension with a concentration of 40 mg/mL, the labeled dose would be contained in 0.1 mL, which would not exceed 0.4 mL and would, therefore, be considered a low volume dose. We propose that this definition of low volume dose apply even if the drug is further diluted after removal from the vial and prior to administration because, even if the dose is further diluted, a dose withdrawn from the vial and diluted would still have the same physical constraints as a dose that was not diluted, and those constraints would necessitate the loss of product as described in the previous paragraph. In addition, we propose that for a drug to meet these unique circumstances, all labeled doses of the drug would be low volume doses. As proposed, this definition would not affect the determination of units as defined at section 1847A(b)(2)(B) of the Act and codified at § 414.802, and we note that the statutory definition of unit is exclusive of any diluent without reference to volume measures pertaining to liquids. The proposed definition of low volume dose would only be applied for the determination of whether a higher applicable percentage is warranted for a drug.

We propose a two-tiered increased applicable percentage for drugs with low volume doses, because the percentage that is unused and discarded for these drugs decreases as the volume of the dose increases. We propose that, for drugs with labeled doses contained within 0.1 mL or less when removed from the vial or container, the applicable percentage be increased to 90 percent. We are proposing 90 percent applicable percentage for this tier because certain drugs with low volume doses of 0.1 mL or less have up to 90 percent of the labeled amount that is unused and discarded and not part of the labeled dose available to be administered.[107] [108] We are not proposing to add an additional 10 percent to this number as we did in the case of hydrogel, as discussed in the CY 2023 final rule (see 87 FR 69729), because, generally, we do not believe it would be appropriate for any product to have an applicable percentage of 100 percent. Such an applicable percentage would, in effect, exclude drugs from the refund liability altogether. We believe it would be inappropriate to effectively expand the list of exclusions described in section 1847A(h)(8)(B) of the Act by proposing an increased applicable percentage of 100 percent to drugs not expressly excluded in statute. However, we considered whether some additional percentage might be appropriate in this case. We solicit comment on whether an additional percentage above 90 percent (but less than 100 percent) is warranted for drugs with low volume doses of 0.1 mL or less.

In the second tier of the low volume dose unique circumstances, we propose that for drugs with labeled doses contained within 0.11–0.4 mL, the applicable percentage be increased to 45 percent. Certain drugs currently marketed that fall into this category have up to 35.6 percent of the labeled amount that is unused and discarded and not part of the labeled dose to be administered. In the same manner as the applicable percentage for the hydrogel finalized in the CY 2023 PFS final rule, we propose to add the discarded amount percentage to the applicable percentage of 10 percent that is used for drugs without unique circumstances (that is, 35.6 percent plus 10 percent), and we propose to round that number to an applicable percentage of 45 percent for this tier.

In summary, we propose to increase the applicable percentages for drugs with a low volume dose (a dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL). Specifically, we propose that:

- Refundable drugs with labeled doses that are contained within 0.1 mL or less when removed from the vial or container have an increased applicable percentage of 90 percent and;
- Refundable drugs with labeled doses that are contained within 0.11—0.4 mL when removed from the vial or container have an increased applicable percentage of 45 percent.

To date, we have identified certain drugs that would meet the proposed criteria for such unique circumstances and would have a proposed increased applicable percentage of 90 percent, including Triesence® (triamcinolone acetonide injection, suspension) and Xipere® (triamcinolone acetonide injection, suspension), along with some other ophthalmic drugs with such low volume doses that do not include all of the target fill volume in the labeled amount (that is, those that are labeled such that the low volume dose is equal to the labeled amount). We also note that, although Susvimo™ (ranibizumab injection, solution) would qualify for the proposed 90 percent applicable percentage, it is excluded from the definition of refundable drug due to filtration requirements as discussed in the 2023 PFS final rule (87 FR 69723 through 69724). To date, we have identified certain drugs that would meet the proposed criteria for such unique circumstances and would have a proposed increased applicable percentage of 45 percent, including Xiaflex® (collagenase clostridium histolyticum) and Kimmtrak® (tebentafusp injection, solution, concentrate).

The second categorical unique circumstances we are proposing is for orphan drugs administered to a low volume of unique beneficiaries, which we propose to be fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year (hereafter referred to as rarely utilized orphan drugs); we propose an increased applicable percentage of 26 percent for drugs with these unique circumstances. There is a higher probability that the percentage of discarded amounts for rarely utilized orphan drugs may not have a normal statistical distribution from quarter to quarter, which could disproportionately affect manufacturers of such drugs by resulting in highly variable refund amounts as compared with the variability of drugs administered to a

[107] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211950Orig1s000correctedlbl.pdf.*

[108] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/022223,022048lbl.pdf.*

higher number of beneficiaries. This is evidenced by our analysis of quarterly discarded drug data reported using the JW modifier of 30 refundable drugs identified in the 2021 Medicare Part B Discarded Drug Units data with greater than 10 percent units discarded,[109] three of which were orphan drugs furnished to a patient population of less than 100 unique fee-for-service Medicare beneficiaries in CY 2021: J9262 (*omacetaxine mepesuccinate*); J9269 (*tagraxofusp-erzs*); and J0223 (*givosiran*). This analysis of JW modifier data for quarters in 2021 and 2022 showed that the average standard deviation of the percentage of units discarded across quarters for the rarely utilized orphan drugs is 6.21 percent, compared with an average standard deviation for all other refundable drugs (with a percentage of discarded units over 10 percent in 2021) of 2.35 percent. In other words, the standard deviation from the mean discarded drug percentage for rarely utilized orphan drugs is 2.64 times greater than that of the group of refundable drugs with larger patient populations and claims volume. In addition, based on the 2021 Medicare Part B Discarded Drug Units data for the three aforementioned drugs, the most historical public data is associated with J9262, which shows that the percent discarded units for J9262 was 23.65 percent, 19.96 percent, and 30.98 percent in 2019, 2020, and 2021, respectively. Because of this substantial statistical variation from quarter to quarter for such drugs, we believe it would be difficult to optimize the presentation of the drug to consistently minimize the discarded amounts to less than 10 percent given the small number of patients receiving the drug. We consider the higher percentage of unused and discarded amounts from such drugs as unavoidable loss due to both the low volume of unique beneficiaries receiving the drug contributing statistically higher variability in discarded amounts. Also, due to the low numbers of patients available to study for rare disease, it may be more difficult to determine the most efficient vial size for the patient population who receive the drug post-marketing. This is similar to the loss of product due to filtration described in section 1847A(8)(B)(ii) of the Act because the loss is unavoidable in both circumstances. In the case of filtration described in statute, the loss is unavoidable because certain amounts of product will be left within the filter and unavailable for administration; in the case of rarely utilized orphan drugs, the loss is unavoidable because of the variability of potential doses (and low number of patients receiving the drug) leading to an inability to develop a package size that will result in a consistent average percentage of discarded units (as evidenced in the analysis above in this section). In contrast, drugs administered to a larger number of beneficiaries per year do have a more consistent average percentage discarded from quarter to quarter, as evidenced by the lower standard deviation in our analysis, and we believe manufacturers are able to develop availability of the drug accordingly to minimize discarded amounts.

We propose that unique circumstances of rarely utilized orphan drugs have the following characteristics: (1) a drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as a drug for a rare disease or condition; and (2) that is furnished to fewer than 100 unique Medicare fee-for-service beneficiaries per calendar year. We propose that the number of beneficiaries receiving such drug in the calendar year would correspond with the refund quarter. For example, for refund quarters in 2023, we would use the number of beneficiaries receiving the drug in the 2023 calendar year to determine if the unique circumstances and increased applicable percentage would apply. Data of number of beneficiaries would be analyzed at the same time as the JW modifier data for the given calendar quarters. To meet these unique circumstances, we propose that the drug be designated an orphan-drug under section 526 of the FD&C Act for a rare disease or condition (or diseases or conditions) and be approved by the FDA-only for one or more indications within such designated rare disease or condition (or diseases or conditions). That is, all FDA-labeled indications for the drug must be orphan indications. In addition, we propose that the drug would meet these unique circumstances and that the increased applicable percentage would apply for as long as the drug meets these conditions, even after any orphan-drug exclusivity end date.

The increased applicable percentage of 26 percent that we are proposing is appropriate because the standard deviation from the mean discarded drug percentage for rarely utilized orphan drugs is 2.64 times greater than that of the larger group of refundable drugs, and multiplying the applicable percentage referenced in paragraph (h)(3)(B)(i)(II) by how many times greater the variance is (in other words, 10 percent times 2.64) equals 26.4 percent, which we propose to round to the nearest percentage.

We propose that CMS would identify drugs that have unique circumstances of low volume doses and rarely utilized orphan drugs in the report sent to manufacturers and apply the proposed increased applicable percentages based on these categorical unique circumstances proposals. If a manufacturer believes that the incorrect applicable percentage was applied to the refund calculation, the manufacturer may submit a dispute regarding the calculation by submitting an error report (see § 414.940(e)).

We propose to codify these applicable percentages at § 414.940(d). Specifically, we propose to add applicable percentages for low volume doses by creating new paragraphs (d)(3) and (4); and we propose to add applicable percentage for orphan drugs administered to fewer than 100 unique beneficiaries per calendar year in new paragraph (d)(5). We propose that these applicable percentages apply beginning with the initial refund report that we propose to be sent no later than December 31, 2024.

We solicit comments on the proposed categorical unique circumstances. Specifically, we solicit comment on the proposed volume (mL) tiers for drugs with low volume doses along with the proposed increased applicable percentages and whether an additional percentage above 90 percent (but less than 100 percent) is warranted for drugs with low volume doses of 0.1 mL or less. We also solicit comment on the increased applicable percentage of 26 percent for rarely utilized orphan drugs.

(4) Proposed Application Process for Individual Drugs

In addition to the two proposed categorical unique circumstances, we propose to establish an application process through which manufacturers may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. We believe manufacturers would benefit from a formal process through which they can provide information, including that which may not be publicly available, and therefore, not known to us, in order to request an increase in their refundable drug's applicable percentage and provide justification for why the drug has unique circumstances for which such an increase is appropriate, including in the case of a drug with an applicable percentage that has already been increased by virtue of

[109] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

its inclusion in categorical unique circumstances.

We propose that, to request CMS consider increasing the applicable percentage of a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling for the drug; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification could include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study. We propose that in evaluating requests for increased applicable percentages, we would review the documentation referenced above for evidence that amounts of drug identified in the FDA-approved package or labeling has similar loss of product as that described in paragraph section 1847A(8)(B)(ii) of the Act.

Section 1847(h)(3)(B)(ii) of the Act requires that any increase to applicable percentages for refundable drugs to be made through notice-and-comment rulemaking. Therefore, we propose that applications for individual applicable percentage increases be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply (for example, applications for increased applicable percentages effective January 1, 2025 would be due to CMS by February 1, 2024). We propose to discuss our analyses of applications in the PFS rulemaking immediately following the application period, and to communicate in the proposed rule whether we consider the drug to have unique circumstances that warrant an increased applicable percentage. We would also include proposals, if any, for increased applicable percentages, along with a summary of any applications for which we determined not to propose an increase in the applicable percentage. We propose to codify this application process for individual unique circumstances in new paragraph § 414.940(e).

We do not consider the following to be unique circumstances warranting an increased applicable percentage at this time: weight-based doses, BSA-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity because we believe manufacturers can optimize the availability of products for these circumstances to limit the percentage of discarded units for a drug, unlike the circumstances of manufacturers of drugs that require filtration during the preparation process, as described in section 1847A(h)(8)(B)(ii) of the Act. FDA draft guidance, titled ''Optimizing the Dosage of Human Prescriptions Drugs and Biological Products for the Treatment of Oncologic Diseases'',[110] states: ''Various dose strengths should be available to allow multiple dosages to be evaluated in clinical trials. Perceived difficulty in manufacturing multiple dose strengths is an insufficient rationale for not comparing multiple dosages in clinical trials.'' Although optimization of dosage and available product formulations most often occurs prior to marketing a drug, we also observe several instances where the drug formulation availability has been changed and subsequently resulted in a decreased percentage of discarded amounts. For example, Kyprolis® (carfilzomib), which is cross-walked to the billing and payment code J9047, was available in only one 60-mg single-dose vial size when first approved in 2012.[111] Subsequently, a second 30-mg vial size was approved in 2016,[112] and a third 10-mg vial size was approved in June of 2018.[113] We observe in discarded drug data, based on the JW modifier, that the percentage of discarded units for J9047 was 14.27, 12.68, 5.95, 4, and 3.09 percent in 2017, 2018, 2019, 2020, and 2021, respectively. There is a sharp drop in the percent of discarded units after 2018, which correlates with the introduction of the 10-mg vial. The labeled dose of Kyprolis® is based on the patient's BSA, there is a dose escalation, there are two different dosage schedules (once weekly and twice weekly) each with differing doses, there are dosage modifications for toxicity that involve dose reductions, and there is a dose reduction for patients with hepatic impairment. With these dose variations taken into consideration, the available vial sizes of the drug allow for the percentage of discarded units to remain well below 10 percent after the introduction of the third vial size.

In addition, we observe that, based on the 2021 discarded drug data,[114] as the number of available package sizes increases, the percent discarded decreases (see Table 19). This example is indicative of ways in which manufacturers can optimize package sizes to reduce the percentage of discarded units in the circumstances listed above.

TABLE 19: 2021 Discarded Drug Data for Refundable Drugs and Number of Available Package Sizes

Percent Units Discarded	Number of Refundable Drugs	Percentage of Refundable Drugs with Only One Package Size
> 20%	7	100%
15—19.99%	6	83.33%
10—14.99%	20	75%
5—9.99%	22	45.45%
2—4.99%	47	29.79%

We solicit comments from interested parties on the application process for individual drug unique circumstances. Specifically, we solicit comment on what factors we should use in a framework for considering these

[110] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/optimizing-dosage-human-prescription-drugs-and-biological-products-treatment-oncologic-diseases.*

[111] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202714lbl.pdf.*

[112] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202714s012lbl.pdf.*

[113] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202714s019lbl.pdf.*

[114] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

applications, what factors we should use to assess appropriate increases to applicable percentages, as well as what types of additional or alternative documentation may help us analyze justifications for increased applicable circumstances.

e. Clarification for the Definition of Refundable Drug

As discussed in the CY 2023 PFS final rule (87 FR 69650 through 69655), CMS aims to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes. On January 18, 2023, we held a Town Hall to discuss this issue further and to provide an opportunity to further engage interested parties on this matter and is soliciting additional comments about skin substitutes in this proposed rule. We anticipate addressing coding and payment for skin substitutes in future rulemaking. While we consider making changes to the Medicare Part B payment policies for such products, we propose that billing and payment codes that describe products currently referred to as skin substitutes not be counted for purposes of identifying refundable drugs for calendar quarters during 2023 and 2024. We plan to revisit discarded drug refund obligations for skin substitutes in future rulemaking.

f. Clarification for the Determination of Discarded Amounts and Refund Amounts

Section 1847A(h) of the Act specifies that discarded amounts of refundable drugs are to be determined using a mechanism such as the JW modifier used as of the date of enactment of the Infrastructure Act or any successor modifier that includes such data as determined appropriate by the Secretary. In the CY 2023 PFS final rule (87 FR 69718 through 69719), we finalized our previously existing policy that required billing providers report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023. Since the JW modifier, the mechanism described in section 1847A(h) of the Act, is not required in Medicare Advantage claims for drugs payable under Medicare Part B and there is not a similar mechanism to identify discarded units of such drugs that are billed to Medicare Advantage plans, we are clarifying that the JW modifier requirement does not apply to units billed to Medicare Advantage plans and that the refund amount calculations under section 1847A(h)(3) of the Act will not include units billed to Medicare Advantage plans.

g. Technical Changes

In the CY 2023 PFS final rule (87 FR 70227) we finalized the regulation text for the calculation of the manufacturer refund requirement. That text contained an error in two places, § 414.940(c)(3) and (d), which incorrectly referenced paragraph (c)(1)(ii) of that section in reference to the applicable percentage, rather than paragraph (c)(2). We propose to correct the textual reference in both paragraphs and make additional technical changes to streamline the text. See section III.A.3.d.(1) of this proposed rule for discussion of additional proposed revisions to these provisions.

h. Use of the JW Modifier and JZ Modifier Policy

In the CY 2023 PFS final rule (87 FR 69723), we discussed the applicability of the JW and JZ modifier policy to drugs that are not administered by the billing supplier, including drugs furnished through a covered item of DME that may be administered by the beneficiary. In such cases, suppliers who dispense drugs payable under Medicare Part B do not actually administer the drug, as the claim is typically submitted prior to the administration of the drug, and the billing provider or supplier is not at the site of administration to measure discarded amounts. We stated that since we do not believe it would be appropriate to collect data about discarded amounts from beneficiaries, the reporting requirement does not apply to drugs that are self-administered by a patient or caregiver in the patient's home. In the updated FAQ for the JW/JZ modifier policy [115] released on January 5, 2023, we reiterated that suppliers who dispense but do not actually administer a separately payable drug are not expected to report the JW modifier.

Beginning October 1, 2023, we will begin editing for correct use of both the JW and JZ modifiers for billing and payment codes for drugs from single-dose containers (87 FR 69719). However, because currently there is no claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier, the policy finalized last year exempting self-administered drugs from the JW/JZ modifier policy may result in claims rejections absent a modification. Therefore, as we continue to believe it is unreasonable to collect discarded drug data from beneficiaries, we propose to require that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. We note, as discussed in section III.B.2.b. of this proposed rule, effective January 1, 2024 RHC and FQHC practitioners can also be licensed marriage and family therapists or mental health counselors. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to new payment limits on the AIR, and this limit will be determined for each RHC in accordance with section 1833(f) of the Act.

FQHCs were paid under the same AIR methodology until October 1, 2014.

[115] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated and an AIR is derived from these aggregate expenditures. The FQHC PPS base rate is updated annually by the percentage increase in the FQHC market basket less a productivity adjustment.

2. Implementation of the Consolidated Appropriations Act (CAA), 2023

a. Section 4113 of the Consolidated Appropriations Act, 2023

In the CY 2022 PFS final rule with comment (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar mental health services furnished under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. In addition, we revised the regulation under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record (86 FR 65210 and 65211).

We also revised the regulation under § 405.2469, FQHC supplemental payments, to state that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. At § 405.2469, we also revised paragraph (d) to describe the same in-person visit requirement referenced in § 405.2463.

As discussed in the CY 2023 PFS final rule (87 FR 69738), the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) included the extension of a number of Medicare telehealth flexibilities established during the public health emergency (PHE) for COVID–19 for a limited 151-day period beginning on the first day after the end of the PHE for COVID–19. Specifically, Division P, Title III, section 304 of the CAA, 2022, delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology until the 152nd day after the end of the PHE for COVID–19. Therefore, in the CY 2023 PFS final rule (87 FR 69737), we revised the regulations under §§ 405.2463 and 405.2469 again to reflect these provisions.

The CAA, 2023 (Pub. L. 117–328, December 29, 2022) extends the Medicare telehealth flexibilities enacted in the CAA, 2022 for a period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024, if the PHE ends prior to that date. Specifically related to RHCs and FQHCs, section 4113(c) of the CAA, 2023 amends section 1834(m)(8) of the Act to extend payment for telehealth services furnished by FQHCs and RHCs for the period beginning on the first day after the end of the COVID–19 PHE and ending on December 31, 2024 if the PHE ends prior to that date. Payment continues to be made under the methodology established for telehealth services furnished by FQHCs and RHCs during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS. We do not believe it necessary to conform the regulation to this temporary provision. Rather, we used our authority in section 4113(h) of the CAA, 2023 to issue program instructions or other subregulatory guidance to effectuate this provision to ensure a smooth transition after the PHE.[116]

Section 4113(d) of the CAA, 2023 also continues to delay the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology. That is, for RHCs and FQHCs, in-person visits will not be required until January 1, 2025 or, if later, the first day after the end of the PHE for COVID–19. Therefore, we continue to apply the delay of the in-person requirements under Medicare for mental health services furnished by RHCs and FQHCs. We note, the Department of Health and Human Services declared an end to the Federal PHE for COVID–19 under section 319 of the Public Health Service Act on May 11, 2023.[117]

We are proposing to make conforming regulatory text changes based on CAA, 2023 to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically, at § 405.2463, ''What constitutes a visit,'' we are proposing to amend paragraph (b)(3) and, at § 405.2469 ''FQHC supplemental payments,'' we are proposing to amend paragraph (d) to include the delay of the in-person requirements for mental

[116] *https://www.cms.gov/files/document/rural-health-clinics-and-federally-qualified-health-centers-cms-flexibilities-fight-covid-19.pdf.*

[117] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

health visits furnished by RHCs and FQHCs through telecommunication technology under Medicare beginning January 1, 2025. We note that we are not revising the regulation text to reflect ''or, if later, the first day after the end of the PHE for COVID–19'' as the legislation states since the end of the PHE was May 11, 2023.

In the CY 2023 PFS final rule (87 FR 69738), we listed the several other provisions of the CAA, 2022 that apply to telehealth services (those that are not mental health visits) furnished by RHCs and FQHCs. For details on the other Medicare telehealth provisions in the CAA, 2022, see section II.D. of this proposed rule. The CAA, 2023 extends the telehealth policies mentioned above and enacted in the CAA, 2022 through December 31, 2024 if the PHE ends prior to that date.

b. Direct Supervision via Use of Two-Way Audio/Video Communications Technology

As discussed in section II.D.2.a of this proposed rule, under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner. For RHCs and FQHCs, services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care management services which may be furnished under general supervision (§ 405.2415(a)(5)). The ''incident to'' policy for RHCs and FQHCs is discussed in Pub. 100–02, chapter 13, section 120.1. Similar to physician services paid under the PFS, outside the circumstances of the PHE, direct supervision of RHC and FQHC services does not require the physician to be present in the same room. However, the physician must be in the RHC or FQHC and immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished to a beneficiary.

During the COVID–19 PHE, the modifications that we made to the regulatory definition of direct supervision for services paid under the PFS were also applicable to RHCs and FQHCs. We explained in the April 6, 2020 IFC that given the circumstances of the PHE for the COVID–19 pandemic, we recognized that in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology. We believed that the same concerns existed for RHCs and FQHCs. In the April 6, 2020 IFC, we allowed the supervising professional to be immediately available through virtual presence using two-way, real time audio-visual technology, instead of requiring their physical presence (85 FR 19245 and 19246).[118] When discussing direct supervision in RHCs and FQHCs, we noted that in general, CMS had modified the requirements for direct supervision to include the use of a virtual supervisory presence through the use of interactive audio and video telecommunications technology.[119]

We believe that extending this definition of direct supervision for RHCs and FQHCs through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023 and we are concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2023, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID–19. We also believe that RHCs and FQHCs will need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. For RHCs and FQHCs, we are proposing to continue to define ''immediate availability'' as including real-time audio and visual interactive telecommunications through December 31, 2024.

In the absence of evidence that patient safety is compromised by virtual direct supervision, we believe that an immediate reversion to the pre-PHE definition of direct supervision may present a barrier to access services, such as those furnished incident-to a physician's service. Therefore, we are soliciting comment on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. When compared to professionals paid under the PFS, RHCs and FQHCs have a different model of care and payment structure. Therefore, we seek comment from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary personnel are performing the supervised service. We are also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

c. Section 4121 of the CAA, 2023

Section 1861(aa) of the Act provides authority under Medicare Part B to cover and pay for RHC and FQHC services. Section 1861(aa)(1) of the Act defines these services as those furnished by physicians, physician assistants, nurse practitioners, nurse-midwives, qualified clinical psychologists, clinical social workers, and services and supplies furnished incident to professional services of these practitioners. As discussed in section III.B.1.a. of this proposed rule, our conforming regulation text is provided in 42 CFR part 405, subpart X where we define RHC and FQHC visits as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished.

Before passage of CAA, 2023, there was no separate benefit category under the statute that recognized the professional services of licensed marriage and family therapists (MFTs) or mental health counselors (MHCs). As discussed in the CY 2023 PFS final rule (87 FR 69546), payment for MFTs was only made under the PFS indirectly when an MFT or MHC performed services as auxiliary personnel incident to the services of a physician or other practitioner and under general supervision. This is also true for RHCs and FQHCs, in that MFTs and MHCs were considered auxiliary personnel and the services they provided were considered incident to the services of the RHC or FQHC practitioner (§ 405.2413).

Section 4121 of Division FF, Title IV, Subtitle C of the CAA, 2023, entitled ''Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program'', amended section 1861(s)(2) of the Act to establish coverage of MFT and MHC services (section 1861(s)(2)(II) of the Act). We note that section II.J of this proposed rule provides a detailed discussion of the provisions in section 4121(a) of CAA, 2023 including the authority for coverage of MFT and MHC services, definitions of these professionals and

[118] *https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf.*

[119] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

their services, and payment under the PFS. Section 4121(b) of CAA, 2023 amended section 1861(aa)(1)(B) of the Act by extending the scope of RHC services to include those furnished by MFTs and MHCs as eligible for payment, which is incorporated into FQHC services through section 1861(aa)(3)(A) of the Act. We are proposing to codify payment provisions for MFTs and MHCs under 42 CFR part 405, subpart X beginning January 1, 2024. That is, RHC and FQHCs would be paid under the RHC AIR and FQHC prospective payment system (PPS), respectively, when MFTs and MHCs furnished RHC and FQHC services defined in §§ 405.2411 and 405.2446. As eligible RHC and FQHC practitioners, MFTs and MHCs would follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW.

In addition, as discussed in section II.J of this proposed rule, we are proposing to allow addiction counselors that meet all of the applicable requirements of clinical supervised experience in mental health counseling, and that are licensed or certified as MHCs, clinical professional counselors, or professional counselors by the State in which the services are furnished) to enroll in Medicare as MHCs. Therefore, to remain consistent with payment policies for professionals billing Medicare under the PFS, we propose that the definitions established for MFTs and MHCs under the PFS would also apply for RHCs and FQHCs. In the CY 2023 PFS final rule (87 FR 69735 through 69737), we discussed the coding and payment for HCPCS code G0323 which describes general BHI services performed by CPs and CSWs under the PFS. We noted CPs and CSWs are statutorily authorized to furnish services in RHCs and FQHCs under sections 1861(aa)(1) and (3) of the Act, respectively, and as described by § 405.2411(a)(6). We also explained, the payment rate for HCPCS code G0323 is based on the payment rate for the current general BHI code, 99484. Therefore, in the CY 2023 PFS final rule (87 FR 69737) we clarified that when CPs and CSWs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. We further stated RHCs and FQHCs that furnish general BHI services are able to bill for this service using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2023.

We note that in section II.J of this proposed rule, we are proposing to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service. Since MFTs and MHCs are statutorily authorized to furnish services in RHCs and FQHCs effective January 1, 2024, we are proposing to clarify that when MFTs and MHCs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511. We believe that this policy aligns to our effort to be consistent with the new services that are proposed for practitioners billing under the PFS.

We propose to make several conforming regulatory changes to applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically:

- At § 405.2401, Scope and definitions, we propose to amend the section to add definitions for MFT and MHC;
- At § 405.2411, Scope of benefits, we propose to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2415, Incident to services and direct supervision, we propose to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2446, Scope of services, we propose to amend the section to include MFT and MHC services to the scope of services;
- At § 405.2448, Preventive primary services, we propose to amend the section to include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2450, Clinical psychologist and clinical social worker services, we propose to amend the section title to add MFT and MHC and include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2452, Services and supplies incident to clinical psychologist and clinical social worker services, we propose to amend the section title to add MFT and MHC and include MFT and MHC where other RHC and FQHC practitioners are stated;
- At § 405.2463, What constitutes a visit, we propose to amend the section to add MFT and MHC to the list of eligible practitioners; and
- At § 405.2468, Allowable costs, we propose to amend the section to add MFTs and MHCs where other RHC and FQHC practitioners are listed.

d. Section 4124 of the Consolidated Appropriations Act, 2023

Section 4124 of Division FF of the CAA, 2023 establishes coverage and payment under Medicare for the Intensive Outpatient Program (IOP) benefit, effective January 1, 2024. IOP may be furnished by hospitals, Community Mental Health Centers (CMHCs), FQHCs and RHCs. Payment for IOP services furnished by RHCs and FQHCs is to be made at the same payment rate as if it were furnished by a hospital.

In addition to existing mental health services furnished by RHCs and FQHCs, this new provision establishes coverage for IOP services furnished in RHCs and FQHCs and includes occupational therapy, family counseling, beneficiary education, diagnostic services and individual and group therapy.

Please see section VIII.F. of the CY 2024 Outpatient Prospective Payment System proposed rule for discussion of the new IOP scope of benefits, requirements, physician certification, and payment policies.

3. Updates to Supervision Requirements for Behavioral Health Services Furnished at RHCs and FQHCs

In the CY 2023 PFS final rule (87 FR 69545 through 69548), we amended the direct supervision requirement under the ''incident to'' regulations for services payable under the PFS to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioner (NPP) when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. Several commenters expressed support for CMS allowing behavioral health services to be furnished under general supervision in the RHC and FQHC settings in addition to services paid under the PFS. In response to the public comments, we noted that for CY 2023, the proposed change to the level of supervision for ''incident to'' behavioral health services from direct to general was applicable only to services payable under the PFS, as services furnished in the RHC and FQHC settings were not addressed in the relevant proposal in the CY 2023 PFS proposed rule (87 FR 46062 through 46068). We stated we may consider changes to the regulations regarding services furnished at RHCs and FQHCs in the future.

Currently, behavioral health services furnished in the RHC and FQHC settings require direct supervision. However, in order to be more consistent with applicable policies under the PFS, for CY 2024, we are proposing to change the required level of supervision for behavioral health services furnished ''incident to'' a physician or NPP's services at RHCs and FQHCs to allow

general supervision, rather than direct supervision, consistent with the policies finalized under the PFS for CY 2023. Accordingly, we are proposing to revise the regulations at §§ 405.2413 and 405.2415 to reflect that behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or another practitioner). Additionally, as discussed in the CY 2023 PFS final rule (87 FR 69547), we note that at § 410.26(a)(1) we define ''auxiliary personnel'' as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other Federally-funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

4. General Care Management Services in RHCs and FQHCs

a. Background

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to independently recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

As we discussed in the CY 2016 PFS final rule (80 FR 71081 through 71088), to address the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not adequately paid for as part of an office visit, beginning on January 1, 2015, practitioners billing under the PFS are paid separately for CCM services when CCM service requirements are met. We explained that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. Although many RHCs and FQHCs pay for coordination of services within their own facilities, and may sometimes help to coordinate services outside their facilities, the type of structured care management services that are now payable under the PFS for patients with multiple chronic conditions, particularly for those who are transitioning from a hospital or SNF back into their communities, are generally not included in the RHC or FQHC payment. Therefore, separate payment was established in the CY 2016 PFS final rule (80 FR 71080 through 71088) for RHCs and FQHCs that furnish CCM services. We believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

In the CY 2018 PFS final rule (82 FR 53169 and 53180), we finalized revisions to the payment methodology for CCM services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2018. We also initiated the use of HCPCS code G0511, a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. In the CY 2019 PFS final rule (83 FR 59683), we explained for CY 2018 the payment amount for HCPCS code G0511 was set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. That is, for CY 2018 the 3 codes that comprised HCPCS code G0511 were CPT code 99490 (*20 minutes or more of CCM services*), CPT code 99487 (*60 minutes or more of complex CCM services*), and CPT code 99484 (*20 minutes or more of BHI services*).

We also explained that another CCM code was introduced for practitioners billing under the PFS, CPT code 99491, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487 (83 FR 56983). Therefore, for RHCs and FQHCs, we added CPT code 99491 as a general care management service and included it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs were paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 (83 FR 59687).

In the CY 2021 PFS final rule (85 FR 84697 through 84699), we explained that the requirements described by the codes for Principal Care Management (PCM) services were similar to the requirements for the services described by HCPCS code G0511; therefore, we added HCPCS codes G2064 and G2065 to HCPCS code G0511 as general care management services for RHCs and FQHCs. Consequently, effective January 1, 2021, RHCs and FQHCs are paid when a minimum of 30 minutes of qualifying PCM services are furnished during a calendar month. The payment rate for HCPCS code G0511 for CY 2021 was the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and PCM codes (HCPCS codes G2064 and G2065). We note that in the CY 2022 PFS final rule (86 FR 65118), HCPCS codes G2064 and G2065 were replaced by CPT codes 99424 and 99435. Therefore, for CY 2022 the payment rate for HCPCS code G0511 was the average of the national non-facility PFS payment rate for CPT codes 99490, 99487, 99484, 99491, 99424, and 99425).

Most recently, in the CY 2023 PFS final rule (87 FR 69735 through 69737), we included Chronic Pain Management (CPM) services described by HCPCS code G3002 in the general care management HCPCS code G0511 when at least 30 minutes of qualifying non-face-to-face CPM services are furnished during a calendar month. We explained since HCPCS code G3002 is valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there was no change made to the average used to calculate the HCPCS code G0511 payment rate to reflect CPM services.

Additional information on care management requirements is available on the CMS Care Management web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html* and on the CMS RHC

and FQHC web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html.*

b. Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) Services Furnished in RHCs and FQHCs

In recent years under the PFS, we have finalized payment for five CPT codes in the RPM code family. RPM services include the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan (84 FR 62697). Within the suite of services that comprise RPM, there is a CPT code that describes the initial set-up and patient education on use of the equipment that stores the physiologic data.

After analyzing and interpreting a patient's remotely collected physiologic data, we noted that the next step in the process of RPM is the development of a treatment plan that is informed by the analysis and interpretation of the patient's data. It is at this point that the physician or other practitioner develops a treatment plan with the patient and/or caregiver (that is, develops a patient-centered plan of care) and then manages the plan until the targeted goals of the treatment plan are attained, which signals the end of the episode of care.

TABLE 20: RPM HCPCS Codes and Descriptors

HCPCS code	Short Description	Official Long Description
99453	Rem mntr physiol param setup	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial set-up and patient education on use of equipment
99454	Rem mntr physiol param dev	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
99457	Rem physiol mntr 1st 20 min	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Rem physiol mntr ea addl 20	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)
99091	Collj & interpj data ea 30 d	Collection and interpretation of physiologic data (e.g. Blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days

Remote Therapeutic Monitoring (RTM) is a family of five codes finalized for Medicare payment in the CY 2022 PFS final rule (86 FR 65114 through 65117). The RTM codes include three practice expense (PE)-only codes and two professional work, treatment management codes. RTM services involve remote monitoring of respiratory system status, musculoskeletal status, therapy adherence, or therapy response. There is also a CPT code that describes the initial set-up and patient education on use of the equipment that stores the physiologic data within the suite of services that comprise RTM.

TABLE 21: RTM HCPCS Codes and Descriptors

HCPCS code	Short Description	Official Long Description
98975	Rem ther mntr 1st setup&edu	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	Rem ther mntr dev sply resp	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Rem ther mntr dv sply mscskl	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
98980	Rem ther mntr 1st 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Rem ther mntr ea addl 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (list separately in addition to code for primary procedure)

Currently, RPM and RTM services are not stand-alone billable visits in RHCs and FQHCs. When these services are furnished incident to an RHC or FQHC visit, payment is included in the RHC's AIR subject to a payment-limit or the per visit payment under the FQHC PPS which is the lesser of the PPS rate or the FQHC's actual charges.

In recent years, we have updated RHC and FQHC policies to improve payment for care management and coordination. We have provided a separate payment to RHCs and FQHCs in addition to the billable visit in part for monthly care management and behavioral health integration codes, as described in the general care management code, HCPCS code G0511, because these are inherently non-face-to-face services that may not be accounted for in the per-visit payment for an in-person encounter.

RHCs and FQHCs have inquired about receiving a separate payment for RTM and RPM services. They have stated that CMS should expand HCPCS code G0511 to include RPM treatment management services to provide Medicare beneficiaries in rural and underserved areas access to these services or establish G-codes to reimburse RHCs and FQHCs for RPM set-up and patient education on use of equipment (CPT code 99453) and monthly data transmission (CPT code 99554) and do not believe that these services are captured in the RHC AIR or FQHC PPS and as such are impeding access to these services.

Upon further review and in line with our thinking about non-face-to-face services previously, we are proposing to include the CPT codes that are associated with the suite of services that comprise RPM and RTM in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs since the requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. Allowing a separate payment for RPM and RTM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of these services.

The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for in-person encounters may not reflect all the services and resources required to furnish comprehensive, coordinated care management. As RPM and RTM services are described, particularly, collection and transmission of data and then further analysis and interpretation of the data are happening outside of the face-to-face visit. RPM and RTM also have principles which are consistent with other care management principles, such as, an established patient-physician relationship is required, patient consent is required at the time that RPM services are furnished, and services allow the monitoring of acute conditions and chronic conditions. However, we note that under this proposal, RPM and RTM services must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. Therefore, we propose that RHCs and FQHCs that furnish RPM and RTM services would be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2024.

c. Services Addressing Health-Related Social Needs: Community Health Integration Services and Principal Illness Navigation Services

(1) Background

As discussed in section II.E.4.(27) of this proposed rule, in recent years, we have sought to recognize significant changes in health care practice and been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment for care management/coordination and primary care services under the PFS. In congruence with services paid under the PFS, we have similarly provided separate payment for transitional care management services, chronic care management services, and behavioral health care management services (discussed above in section III.B.4.a. of the proposed rule) to improve payment accuracy to better recognize resources involved in care management and coordination for certain patient populations. In this effort to improve payment accuracy for care coordination in RHCs and FQHCs, we are exploring ways to better identify the resources for

helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with their ability to execute a medically necessary plan of care. RHCs and FQHCs sometimes obtain information about and help address, social determinants of health (SDOH) that significantly impact their ability to diagnose or treat a patient. The CPT E/M Guidelines defined SDOH as, ''Economic and social conditions that influence the health of people and communities. Examples may include food or housing insecurity. Additionally, RHCs and FQHCs sometimes help newly diagnosed cancer patients and other patients with similarly serious, high-risk illnesses navigate their care, such as helping them understand and implement the plan of care, and locate and reach the right practitioners and providers to access recommended treatments and diagnostic services, considering the personal circumstances of each patient. Payment for these activities, to the extent they are reasonable and necessary for the diagnosis and treatment of the patient's illness or injury, is currently included in the RHC AIR or under the FQHC PPS payment amount for visits and some care management services. Medical practice has evolved to increasingly recognize the importance of these activities, and we believe RHCs and FQHCs are performing them more often.

However, this work is not explicitly identified in current coding, and as such, we believe it is underutilized and undervalued. Accordingly, we are proposing to create new coding to expressly identify and value these services for PFS payment, and distinguish them from current care management services. Therefore, we are considering the new coding for purposes of payment to RHCs and FQHCs.

(2) Payment for Community Health Integration (CHI) Services in RHCs and FQHCs

Consistent with the discussion in section II.E.4.(27).b. of this proposed rule, there are two new HCPCS codes proposed to describe CHI services performed by certified or trained auxiliary personnel, which may include a CHW, incident to the professional services and under the general supervision of the billing practitioner. The requirements for the proposed CHI services, as stated in section II.E.4.(27) of this proposed rule, are similar to the requirements for the general care management services furnished by RHCs and FQHCs. As such, we believe the level of care coordination resources required in addressing the particular SDOH need(s) that are interfering with, or presenting a barrier to, diagnosis or treatment of the patient's problem(s) addressed in the CHI initiating visit are not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Payment for office visits may not reflect all the services and resources involved with CHI as described in the HCPCS code below, for example, coordination of care, facilitation of access to services, communication between settings.

GXXX1 Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating
E/M visit.

++ Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

- Practitioner, Home-, and Community-Based Care Coordination.

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (*e.g.,* housing, utilities, transportation, food assistance) to address the SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

(3) Payment for Principal Illness Navigation (PIN) Services in RHCs and FQHCs

Consistent with the discussion in section II.E.4.(27).e. of this proposed rule, there are two new HCPCS codes proposed to describe PIN services. That is when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or

nursing home placement, acute exacerbation/decompensation, functional decline, or death. The requirements for the proposed PIN services are also similar to the requirements for the general care management services furnished by RHCs and FQHCs.

As such, we believe the resources required to provide the level of care coordination needed for individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely are not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Payment for office visits may not reflect all the services and resources involved with PIN as described in the HCPCS code below.

GXXX3 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal setting and establishing an action plan.

++ Providing tailored support as needed to accomplish the practitioner's treatment plan.

- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Coordination.*

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).

++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access/health system navigation.*

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.

++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

Allowing a separate payment for CHI and PIN services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services. In an effort to be consistent with the new services that are being proposed for practitioners billing under the PFS, we are proposing to include PIN services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs.

We note that under the proposals to expand the billable services under HCPCS code G0511 to include CHI and PIN, each of these services must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. We expect that our proposal to add the new codes for CHI and PIN to the general care management code would also support the CMS pillars [120] for equity, inclusion, and access to care for the Medicare population, and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care.

d. Proposed Revision to the Calculation of the Payment Amount for the General Care Management HCPCS Code G0511

Currently, HCPCS code G0511 is based on the PFS national average non-facility payment rate for each of the services identified as billable general care management services. Then we add each payment rate and divide by the total number of codes to arrive at the payment amount for HCPCS code G0511. This payment amount is a flat rate that is not subsequently adjusted for locality. As we noted in the CY 2023 PFS final rule (87 FR 69735), when determining which services are billable under HCPCS code G0511, we do not include the add-on HCPCS codes payable under the PFS because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners. Instead we generally include the base codes. In the CY 2023 PFS final rule (87 FR 69736), we mentioned that we may consider other approaches for calculating the payment rate for HCPCS code G0511 as the number of services included in the general care management code is growing each year and provided examples. We thought to consider in the future valuing HCPCS code G0511 using a weighted average of the services that comprise HCPCS code G0511 or using the national average of the top three services comprising HCPCS code G0511. We welcomed comments on potential methodologies, but noted we did not receive any comments.

As we discuss above, we have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate

[120] CMS Strategic Plan. *https://www.cms.gov/cms-strategic-plan.*

payment in the PFS to separately recognize and pay for these important services. The care coordination included in services, such as office visits, do not always adequately describe the non-face-to-face care management work involved in primary care. Payment for in-person encounters may not reflect all the services and resources required to furnish comprehensive, coordinated care management. Through the last few payment rules, we have expanded the general care management services billable using the HCPCS code G0511 to be consistent with the policies implemented under the PFS.

In section III.B.4.b and c. of this proposed rule, we are proposing to expand the billable services under HCPCS code G0511 to include RPM, RTM, CHI, and PIN. If we continue to calculate HCPCS code G0511 using our current approach, we believe that the value may no longer be appropriate payment for those services since we are simply dividing by the number of codes that comprise HCPCS code G0511 and as that number of services with lower payment rates increases, the value diminishes. Therefore, we are proposing to revise our method for calculating HCPCS code G0511 so that payment for general care management is more appropriate. Below, we compare our current method to the proposed revised approach.

Based on the current methodology for HCPCS code G0511 as shown in Table 22, general care management services are paid at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, 99491, 99424 and 99426.

TABLE 22: CY 2023 National Non-Facility PFS Payment Rate for G0511

CPT Code	National Non-Facility PFS Payment Rate
99424	$81.33
99426	$61.34
99484	$43.04
99487	$133.18
99490	$62.69
99491	$85.06
G0511	**$77.94[1]**

[1] Noting when averaging the six codes, the total RVU for HCPCS code G0511 is 2.295. Multiplying that by the conversion factor of 33.8872 results in $77.77. However, RVUs on the PFS file are expressed in two decimal places. Thus, we round the 2.295 average to 2.30 which yields 2.30 * 33.8872, resulting in $77.94, the current payment rate for HCPCS code G0511.

As shown in Table 23, when we include RPM and RTM services in the national non-facility average as discussed above, the payment rate for HCPCS code G0511 is reduced to $64.13 based on the national non-facility PFS payment rates for CY 2023.

TABLE 23: CY 2023 National Non-Facility PFS Payment Rate for G0511 with RPM and RTM Base Codes

CPT Code	National Non-Facility PFS Payment Rate
99454	$50.15
99457	$48.80
99091	$54.22
98976	$50.15
98977	$50.15
98980	$49.48
99424	$81.33
99426	$61.34
99484	$43.04
99487	$133.18
99490	$62.69
99491	$85.06
G0511	**$64.13***

*Noting when averaging the 12 codes, the total RVU for HCPCS code G0511 is 2.30. Multiplying that by the conversion factor of 33.8872 results in $64.13.

As demonstrated by comparing Table 22 to Table 23, using the current method of calculating the average of the non-facility rates but adding in RPM and RTM services base codes would result in a lower payment amount for HCPCS code G0511 compared to the current payment amount. We believe that while the policy may address providing a payment for furnishing non-face-to-face services, the magnitude of the value may not appropriately account for the costs. Therefore, we considered and are proposing a revised methodology for the calculation by looking at the actual utilization of the services. That is, we are proposing to use a weighted average of the services that comprise HCPCS code G0511. In order to use a weighted average, there needs to be data on the utilization of the services. We do not have data on utilization of the services that comprise HCPCS code G0511 for RHCs and FQHCs since HCPCS code G0511 accounts for a variety of services. Therefore, we would use the most recently available utilization data from the services paid under the PFS, that is, in the physician office setting. We believe that the physician office setting provides an appropriate proxy for utilization of these services in the absence of actual data because this setting most closely aligns with the types of services furnished in RHCs and FQHCs since they typically furnish primary care.

In order to analyze utilization for services paid under the PFS and to ensure we accounted for payments accurately, we would use CY 2021 claims data to look at utilization of the base code for the service and any applicable add-on codes used in the same month as well as any base codes reported alone in a month for all of the services encompassing general care management, that is the array of services that make up HCPCS code G0511. We believe we need to account for the payment associated with the base code along with an applicable add-on code in our calculation as this demonstrates a complete encounter. Until actual utilization becomes available, RHCs and FQHCs that furnish CPM, GBHI, CHI and PIN services would report HCPCS code G0511 when those services are furnished; however, they would not be included in the weighted average at this time. Once more data is available, we will revisit the valuation of HCPCS code G0511 to include CPM, GBHI, CHI, and PIN as necessary.

Table 24 shows the payment amount using this calculation. The national non-facility payment rate associated with each code that comprises HCPCS code G0511 can be found in Addendum B of this proposed rule. We note that the revised methodology does reduce the payment rate for HCPCS code G0511 from its current rate for CY 2023, although not significantly.

TABLE 24: Weighted Average Payment Rate for G0511 with RPM, RTM, CHI, and PIN Services Using CY 2023 Rates and Conversion Factor

CPT Code	2021 NF Utilization	Weighted Average
99454	931,411	46,710,262
99457	492,286	24,023,557
99457+99458	398,209	35,221,586
99474	1,581	24,110
99091	55,435	3,005,686
98976	93,141	4,671,028
98977	93,141	4,671,028
98980	14,112	698,243
98980+98981	119,463	10,647,711
99424	13,719	1,115,766
99424+99425	4,573	638,482
99426	28,858	1,770,134
99426+99427	9,619	1,046,382
99484	151,808	6,533,816
99487	26,441	3,521,412
99487+99489	229,004	46,641,245
99490	3,436,429	215,429,734
99490+99439	802,656	88,396,505
99491	29,665	2,523,322
99491+99437	118,661	17,210,562
G0511		**$72.98**

Therefore, we propose to take the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511 by using the CY 2021 PFS utilization to calculate the payment rate for the general care management services furnished in RHCs and FQHCs on or after January 1, 2024. The number on the right side of Table 24 is a weighted average which grants more relative weight to the codes in proportion to their utilization in 2021 claims data. To calculate the weighted average, we multiple the non-facility payment rate times the non-facility utilization for each code, sum this total, then divide by the summed non-facility utilization for the codes included in the average. In an effort to be consistent with practitioners billing under the PFS and to account for the additional time spent in care coordination, we determined that this approach was more accurate representation of the payment. We would also update HCPCS code

G0511 annually based on current data available in the PFS.

We propose revisions at § 405.2464(c) to reflect the revised methodology for calculating the payment amount for general care management services beginning January 1, 2024 which would be based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data. We welcome comments on this proposed methodology.

e. Chronic Care Management Services and Virtual Communication Services Requirement for Obtaining Beneficiary Consent

(1) Chronic Care Management Services

RHCs and FQHCs have been authorized to bill for Chronic Care Management (CCM) services since January 1, 2016. The RHC and FQHC requirements for billing CCM services have generally followed the requirements for practitioners billing under the PFS, with some adaptations based on the RHC and FQHC payment methodologies. In fact, in the CY 2017 PFS final rule (81 FR 80256–80257) to assure that CCM requirements for RHCs and FQHCs were not more burdensome than those for practitioners billing under the PFS, we finalized revisions to the requirements for CCM services furnished by RHCs and FQHCs similar to revisions to the requirements for CCM services finalized under the PFS (81 FR 80243 through 80251). Information regarding CCM services is available on the CMS Care Management Site.[121]

In the CY 2022 PFS proposed rule (86 FR 39175), we solicited public comment on the standard practice used by practitioners to obtain beneficiary consent for CCM services. We stated that we have received questions from interested parties regarding the consent requirements for CCM services. We explained that these questions may have arisen because of the many flexibilities allowed in response to the PHE for COVID–19. In particular, during the PHE for COVID–19, we allowed interested parties to obtain beneficiary consent for certain services under general supervision (85 FR 19230, April 6, 2020). We noted that before the PHE for COVID–19, we required that beneficiary consent be obtained either by or under the direct supervision of the primary care practitioner. We noted that this requirement was consistent with the conditions of payment for this service under the PFS. We stated that as we consider what policies implemented during the PHE for COVID–19 should remain in effect beyond the PHE, we were interested in understanding how billing practitioners furnishing CCM at different service sites (for example, physician office settings, RHCs, FQHCs) have been obtaining beneficiary consent over the past year and how different levels of supervision impact this activity. We welcomed public comment on the issue, specifically on what levels of supervision are necessary to obtain beneficiary consent when furnishing CCM services and said that we will consider such comments in future rulemaking.

We received 52 comments regarding the standard practice used by practitioners to obtain beneficiary consent for CCM services from a variety of interested parties. For example, we received comments from hospitals, physicians, RHCs, FQHCs, software companies, care management companies.

All comments received expressed support for obtaining consent for care management under general supervision. Many commenters requested that CMS make this supervision level permanent after the expiration of the COVID–19 PHE. They stated that their practice would be unable to maintain its current CCM program without the assistance of a third-party partner. CCM vendors have trained enrollment staff which are vital to obtaining proper consent from their patients. Their staff are able to educate and inform our patients regarding the CCM program as they have been specifically trained to explain the benefits of CCM. They explained that vendors have the capacity to call patients and receive calls when it is convenient for the patient. They expressed concern that they could not replicate these services using only their employed staff and that allowing a third party to obtain consent from their patients for CCM under general supervision is vital to their CCM program.

One commenter explained that CCM programs are a challenging and heavy lift for all providers, regardless of size and available resources, and the providers that offer CCM services to their patient populations do so because they recognize and value CCM's capacity to improve patient outcomes. The commenter stated that they have seen the administrative burdens of successful and compliant CCM programs fall hardest upon RHCs and FQHCs and noted if CMS were to establish general supervision as the guideline for beneficiary consent, this would ease those burdens. The commenter noted that CCM codes describing clinical staff activities are assigned general supervision and if CMS were to carve out beneficiary consent from the rest of CCM and impose a heightened administrative burden by imposing direct supervisions, RHCs and FQHCs that service the most vulnerable and underserved patient populations, would encounter challenges that could have negative consequence for their existing CCM programs.

Several commenters stated that they believed an efficient Medicare system requires CCM services to leverage the potential of non-face-to-face modalities, such as EHR systems, patient portals, texting/SMS services, chatbot technologies, interactive mobile medical apps, and direct patient calls. The commenters explained that while they understood CMS' concerns, it is long past due that CMS do away with the requirement for a provider to directly obtain consent. Virtual modalities more than adequately enable a patient to gain an understanding of what they are consenting to at the same level or better than an in-person consent process, making the direct consent requirement outdated and overburdensome. The commenters strongly encouraged CMS to permanently allow providers to obtain beneficiary consent under general supervision.

We note that, for the purposes of CCM services furnished under the PFS, we require that practitioners obtain informed consent before furnishing a beneficiary with CCM services. During the COVID–19 PHE, CMS clarified its existing policy about how practitioners could obtain beneficiary consent. We explained that practitioners could obtain beneficiary consent either at the required initiating visit for CCM (many of which Medicare allows to be furnished virtually), or at the same time that the CCM service is initiated by auxiliary staff who work to furnish the CCM services. When the beneficiary's consent is separately obtained, it may be obtained under the general supervision of the billing practitioner and may be verbal as long as it is documented in the medical record and includes notification of the required information. Now that the COVID–19 PHE has ended, we expect that practitioners will continue to appropriately obtain informed consent before they start furnishing CCM services to a beneficiary.

For purposes of CCM services furnished by RHCs and FQHCs, we are proposing to clarify the policy of how RHC and FQHC practitioners can obtain beneficiary consent. That is, while we have stated our intent since allowing

[121] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

RHCs and FQHCs to furnish CCM services, is to assure that CCM requirements for RHCs and FQHCs were not more burdensome than those for practitioners billing under the PFS, we believe our guidance could be clearer. After a review of commenters' concerns, we propose to clarify when, how and by whom beneficiary consent for CCM services can be obtained. Specifically, informed consent to receive CCM services must be obtained prior to the start of CCM services. Consent does not have to be obtained at the required initiating visit for CCM that must be performed by the RHC or FQHC practitioner, but it can be obtained at that time. Since the RHC or FQHC practitioner discusses CCM with the beneficiary during the initiating visit, if consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification of the required information. That is, beneficiary consent can be obtained at the same time that the CCM service is initiated by auxiliary staff who work to furnish the CCM services. Further, there need not be an employment relationship between the person obtaining the consent and the RHC or FQHC practitioner. That is, the clinical staff obtaining the verbal or written consent can be under contract with the RHC or FQHC.

It is important to reiterate that the importance of obtaining advance beneficiary consent to receive CCM services is to ensure the beneficiary is informed, educated about CCM services, and is aware of applicable cost sharing. In addition, querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. We require the beneficiary be informed on the availability of CCM services; that only one practitioner can furnish and be paid for these services during a calendar month; and of the right to stop the CCM services at any time (effective at the end of the calendar month). Again, we believe that it is important that the beneficiary grant the consent at the onset of CCM services to have the opportunity to understand what services are being billed and note it is important for CMS to take a balanced approach between administrative burden and potential program integrity concerns. That being said, we are clarifying that we understand that the sequencing and mode of consent can take various forms since the beneficiary is given notice and verbally consents.

(2) Virtual Communication Services

In the April 6, 2020 IFC (85 FR 19253 through 19254), we implemented on an interim final basis the expansion of services that can be included in the payment for virtual communications in RHCs and FQHCs. We explained that in order to minimize risks associated with exposure to COVID–19, and to provide the best care possible during the PHE for the COVID–19 pandemic, we believed that RHCs and FQHC practitioners, like many other health care providers, should explore the use of interactive communications technology in the place of services that would have otherwise been furnished in person and reported and paid under the established methodologies.

In order to ensure these services would be available to beneficiaries who otherwise would not have access to clinically appropriate in-person treatment, we placed in our interim final rule a provision stating that all virtual communication services billed by HCPCS code G0071 would be available to new patients not seen by the RHC or FQHC within the previous months and modified requirements regarding when patient consent was required for these services, in order to promote timely provision of care. Specifically, we allowed consent to be obtained when the services were furnished instead of prior to the service being furnished and before the services were billed. Consent could also be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication codes during the COVID–19 PHE.

We received several comments on these policies and subsequently finalized the provisions of the April 6, 2020 IFC without modification. However, we stated that when the COVID–19 PHE ended, beneficiary consent for these services would revert back to direct supervision and clarified this in the CY 2023 PFS final rule with comment period (87 FR 70127 through 70128).

Similar to the discussion above regarding obtaining consent for CCM, we believe the same philosophy applies to consent for virtual communications. In an effort to continue promoting access to timely, quality care for Medicare beneficiaries and to align with the PFS, we propose to clarify that the consent from the beneficiary to receive virtual communication services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. While we continue to believe that beneficiary consent is necessary so that the beneficiary is notified of cost sharing when receiving these services, we do not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services.

C. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs)

1. Summary of the Provisions

Section III.C. of this proposed rule outlines changes to the RHC and FQHC CfCs as required in section 4121 of division FF of the Consolidated Appropriations Act (Pub. L. 117–328, December 29, 2022) (CAA 2023). Specifically, we must implement provisions that would modify the existing RHC and FQHC CfCs at § 491.8(a)(3) to include marriage and family therapists (MFTs) and mental health counselors (MHCs) as part of the collaborative team approach to provide services under Medicare Part B. We also propose to include definitions of other healthcare professionals who are already eligible to provide services at RHCs and FQHCs.

2. Proposed Changes to the RHC Conditions for Certification and FQHC Conditions for Coverage

a. Definitions (§ 491.2)

According to House Report No. 95–548 (Vol. I), the Rural Health Clinic Services Act of 1977 was established to address an inadequate supply of physicians available to serve Medicare and Medicaid beneficiaries in rural and shortage areas. The establishment of RHCs addressed this problem by allowing physicians and certain other practitioners in qualifying clinics in rural, medically underserved communities to furnish outpatient services to Medicare and Medicaid beneficiaries. The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210, enacted December 13, 1977) enacted section 1861(aa) of the Act to extend Medicare entitlement and payment for primary care services furnished at an RHC by physicians and certain other practitioners and for services and supplies incidental to their services. Other practitioners included nurse practitioners (NPs) and physician assistants (PAs). Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists (CPs), clinical social workers (CSWs), and certified nurse midwives (CNMs).

Section 4161(a)(2) of the Omnibus Budget Reconciliation Act (OBRA) of

1990 added the definition of ''FQHC services'' to section 1861(aa) of the Act as ''services described in section 1861(aa)(l)(A) through (C) of the Act,'' which, are RHC services generally provided by physicians, NPs, PAs, CPs, CSWs, and CNMs. FQHCs were established to provide primary care and preventive services in underserved rural or urban areas designated as either a shortage area or an area with a medically underserved population, regardless of the patient's ability to pay.

Section 4121 of division FF of the CAA, 2023 amended section 1861 of the Act to add a new subsection (lll) and corresponding revisions to subsection (s)(2) of such section that establish a new benefit category for MFT services and MHC services. Section 4121(b)(1) of the CAA, 2023 amended section 1861(aa)(1)(B) of the Act to add MFT and MHC services as services that can be furnished by RHCs, which is incorporated into FQHC services through section 1861(aa)(3) of the Act.

Section 1861 of the Act authorizes the Secretary to establish the requirements that an RHC and FQHC must meet to participate in the Medicare Program. These requirements are codified in regulations at 42 CFR part 491. For an RHC and FQHC to receive Medicare payment for services, it must meet the requirements at part 491, which are intended to promote the health and safety of care provided to RHC and FQHC patients.

In order to reflect the statute, we propose adding conforming changes to the CfCs to include MFT and MHC services as proposed in section III.B. of this proposed rule to indicate that RHC and FQHCs can offer these services under their Medicare certification. At § 491.2, *Definitions,* we propose adding a definition of MFTs and MHCs by cross-referencing the definitions proposed at §§ 410.53 and 410.54.

Previously enacted laws extended the definition of covered RHC services to include the services of CPs (section 4077(a) of OBRA '87), CNMs (section 6213(a) of OBRA '89), and CSWs (section 6213(b) of OBRA '89). Note that the CfCs do not currently define CPs, CSWs, or CNMs whose services are covered when furnished in an RHC and FQHC, so we also propose to add these professionals to § 491.2, *Definitions,* and cross-reference the definitions established in the payment requirements at § 410.77(a), § 410.71(d), § 410.73(a) respectively.

We propose revising the existing ''nurse practitioner'' (NP) definition at § 491.2. The current definition sets forth education and certification requirements. The current requirement at § 491.2(1) states that an NP must be certified as a primary care NP by the American Nurses Association and the National Board of Pediatric Nurse Practitioners and Associates. The National Board of Pediatric Nurse Practitioners and Associates has changed the organization's name since this requirement was first implemented. The American Association of Nurse Practitioners (AANP), examined NP graduates from 2019 to 2020 by certification exam and discovered that 88 percent of licensed NPs in the U.S. are educated and prepared in primary care.[122] The AANP considers primary care providers with a population focus on family, adult gerontology primary care, psych mental health, pediatric primary care, and women's health. We believe that removing specific certifying boards from § 491.2(1) will ensure that the requirements reflect the breadth of currently available certifications. For awareness, examples of certifying boards that focus on an area the AANP considers primary care are the American Academy of Nurse Practitioners Certification Board (AANPCB), American Nurses Credentialing Center (ANCC) Certification Program, Pediatric Nursing Certification Board (PNCB), and the National Certification Corporation (NCC).[123] We propose revising the definition of NP at § 491.2(1) to require that an NP, be certified as a primary care nurse practitioner at the time of provision of services by a recognized national certifying body that has established standards for nurse practitioners and possess a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree. We have proposed adding the education requirement to clause (1) of the definition because the American Nurses Association has stated that for someone to become an NP, one must be a registered nurse or have a bachelor of science in nursing (BSN), complete an NP-focused master's or doctoral nursing program, and pass the National NP Certification Board Exam.[124] We propose to retain paragraphs (2) and (3) of the current NP definition, which provides alternative certification and education requirements an NP can meet to furnish services in an RHC or FQHC if (1) is not met.

We are soliciting comments regarding the current definition of NPs at § 491.2(1). Specifically, we are interested in feedback on whether the definition of NPs should specify that an NP's certification be in the area of primary care, or whether this distinction should be removed. This would allow all NPs who are certified by a national certifying body and meet other applicable requirements to furnish services in an RHC or FQHC. We recognize that NPs are one of the fastest-growing provider groups to provide primary care, and the number of Medicare beneficiaries who receive primary care services from NPs is increasing.[125] [126] According to the March 2023 Medicare Payment Policy report, a larger percentage of Medicare beneficiaries and privately insured persons living in rural or low-income areas have revealed that they rely on NPs or PAs for most, if not all, of their healthcare needs. This indicates that NPs and PAs play a crucial role in ensuring that underserved populations have access to quality healthcare services, despite the challenges of living in areas with limited healthcare professionals and resources. The latest report from AANP indicates that a significant proportion of NP graduates are currently certified in primary care; however, during the 2019–2020 academic year, approximately 12.9 percent or 45,795 NP graduates received certification in non-primary care specialties, including Adult Acute Care, Neonatal, and Pediatric Acute Care.[122] The precise number of non-primary care-certified NPs who would furnish their services at RHCs and FQHCs if the primary care certification requirement was removed remains uncertain at this time.

With the increasing number of NPs and their crucial role in providing quality care, the Consensus Model was developed to tackle the issue of inconsistent standards in education, regulation, and practice for advanced practice RNs (APRNs) by providing guidance for states to adopt uniformity in the regulation of APRN roles, licensure, accreditation, certification and education. The aim of the Consensus Model is to promote patient safety while providing greater access to

[122] *https://www.aanp.org/advocacy/advocacy-resource/position-statements/nurse-practitioners-in-primary-care#:~:text=Millions%20of%20Americans%20choose%20a,of%20all%20ages%20and%20backgrounds.*

[123] *https://www.aanp.org/student-resources/np-certification.*

[124] *American Association of Nurse Practitioners (2020). The Path to Becoming a Nurse Practitioner (NP). https://www.aanp.org/news-feed/explore-the-variety-of-career-paths-for-nurse-practitioners#:~:text=To%20become%20an%20NP%2C%20one,national%20NP%20board%20certification%20exam.*

[125] *https://www.bls.gov/careeroutlook/2020/article/careers-for-nurses-opportunities-and-options.htm.*

[126] *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch4_v2_SEC.pdf.*

care by standardizing education, certification, accreditation and licensure requirements for APRNs, including NPs.[127] In order to practice in specialized nursing roles, individuals must possess specialized knowledge and skills. Therefore, the Consensus Model mandates that Advanced Practice Registered Nurses (APRNs) have congruent education, certification, and licensure in terms of population foci. NPs are required to select between two population foci tracks: adult-gerontology and pediatric foci. These foci are further distinguished as either primary care or acute care. Although the focus of practice centers around the patient's needs rather than the setting, NPs possess comprehensive educational training and practical experience to cater to patients in primary or acute care.[128] Primary care NPs are trained to offer comprehensive, continuous care for patients with most health needs, including chronic conditions. In contrast, acute care NPs are equipped to provide restorative care, which involves addressing rapidly changing clinical conditions in patients with unstable, chronic, and complex acute and critical conditions.

The NP scope of practice allows them to provide care to patients based on the acuity of the patient's needs, rather than the setting in which the services are administered. This implies that an acute care NP can offer their services to patients within their scope of practice in RHCs and FQHCs, and other settings. NPs increasingly provide services to Medicare beneficiaries; however, the scope of benefits between primary care and acute care may be different. We seek comments on whether the specification of requiring NPs to be certified in primary care should remain in the definition at § 491.2.

b. Staffing and Staff Responsibilities (§ 491.8)

Section 1861(aa) of the Act extends Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at an RHC by physicians and other practitioners and for services and supplies incidental to their services. Other practitioners include NPs, PAs, CPs, CSWs, and CNMs. Section 4121(b)(1) of the CAA, 2023, *Coverage of Certain Mental Health Services Provided in Certain Settings Rural Health Clinics and Federally Qualified Health Centers* amends section 1861(aa)(1)(B) of the Act by including MFT and MHCs to the list of other practitioners whose services, when provided in RHCs and FQHCs, are entitled to payment under the Medicare program. To implement these changes, we propose modifying our CfCs to include MFT and MHCs as recognized staff for RHC and FQHCs.

The current requirements at § 491.8, *Staffing and staff responsibilities,* establish staffing requirements for RHC and FQHCs, details of physician responsibilities, PA and NP responsibilities, and COVID–19 vaccination requirements for staff. We propose revising the requirements at § 491.8, *Staffing and staff responsibilities.* Currently, at § 491.8(a)(3), the PA, NP, CNM, CSW, or CP may be the owner, employee, or furnish services under contract with the clinic (RHC) or center (FQHC). In the case of a clinic, at least one PA or NP must be an employee of the clinic. At § 491.8(a)(3), we propose to add MFT and MHC to the list, allowing them to be the owner, employee, or furnish services under contract to the clinic or center. Additionally, § 491.8(a)(6) requires that a physician, PA, NP, CNM, CSW, or CP is available to furnish patient care services at all times the clinic or center operates. Furthermore, for RHCs, an NP, PA, or CNM is available to furnish patient care services at least 50 percent of the time the RHC operates. We propose adding MFTs and MHCs to the list of other practitioners who can provide services when the clinic or center is open and operating. We are also proposing to update § 491.8(a)(6) to include MFTs and MHCs to the list of other practitioners who are eligible to furnish services and who can provide services, within the scope of practice, when the clinic or center is open and operating.

Section 1861(aa)(2) and (4) of the Act require that RHC and FQHC staff include one or more physicians, and RHCs are also required to employ at least one PA or NP. There are no requirements for an RHC or FQHC to employ a CNM, CSW, CP, MHC, or MFT; however, we expect clinics and centers to ensure that the needs of the patient population they serve are met. We acknowledge that there are similarities and differences between CSWs, MHCs, and MFTs, ranging from offered services to experience to scope of practice. CSWs, MHCs, and MFTs have similar roles and responsibilities as they relate to counseling and can assist patients with the challenges they are facing; however, MHCs and MFTs may have a larger emphasis on human development and psychological approaches, whereas CSWs often focus on a person's overall social and socioeconomic circumstance. Some other services social workers can provide are psychosocial assessments, identifying and providing community resources to patients, and assisting with communicating with other members of their healthcare team. As rural areas are increasingly diverse, have significant strengths and unique challenges, and are essential in providing care to residents of medically underserved communities, RHCs and FQHCs play a key role in identifying the needs of their patients and employing mental health professionals. In November 2022, we published a framework for advancing health care in rural, tribal, and geographically isolated communities.[129] Priorities related to rural health included in the framework are advancing health equity by addressing health disparities, expanding access to care, and engaging with partners and communities. To reduce health disparities and achieve positive physical, mental, and behavioral health outcomes, providers must address access to affordable and quality food, education, employment, housing, and access to the physical and mental care they need.[130] People living in rural areas have less access to healthcare and social services, higher unemployment rates, and higher poverty rates than urban areas, which impacts a person's physical and mental well-being.[131] [132] [133] To meet an individual's medical, behavioral, and social service needs, it's important to have high-quality staff to address those issues.[134] A team of diverse professionals can address a patient's physical and mental health through counseling, case management, and provide resources and information to address social determinants of health.[135]

Individuals living in rural areas face multiple barriers that prevent people from accessing physical and mental health services, including but not limited to provider shortages and

[127] *https://www.ncbi.nlm.nih.gov/books/NBK209870/.*

[128] *https://www.aacn.org/~/media/aacn-website/certification/advanced-practice/adultgeroacnpcompetencies.pdf.*

[129] *https://www.cms.gov/files/document/cms-geographic-framework.pdf.*

[130] *https://www.jstor.org/stable/pdf/26554276.pdf?refreqid=excelsior%3A3437750e2633ee53aa5c0afe8caae6ea&ab_segments=&origin=&initiator=&acceptTC=1.*

[131] *https://apps.who.int/iris/bitstream/handle/10665/112828/9789241506809_eng.pdf.*

[132] *https://onlinelibrary.wiley.com/doi/10.1111/jmft.12202.*

[133] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4102288/.*

[134] *https://www.chcs.org/media/INSIDE_ICTs_for_Medicare-Medicaid_Enrollees-012216.pdf.*

[135] *https://www.jstor.org/stable/pdf/26554276.pdf?refreqid=excelsior%3A3437750e2633ee53aa5c0afe8caae6ea&ab_segments=&origin=&initiator=&acceptTC=1.*

transportation difficulties.[136] A study from 2015 surveyed mental health specialists in nonmetropolitan areas and found that rural counties had less than half as many mental health professionals as proportional to the population compared to urban areas.[137] The shortage of mental health providers in rural areas also puts a strain on generalist providers to diagnose and care for patients seeking care for mental health.[138] In 2017, general practice physicians (including NPs and PAs) were the predominant source for treating depression in adults living in rural communities.[139] Of the same population, less than 20 percent received treatment from mental health professionals, and 32 percent received no treatment. If MFTs and MHCs can provide reimbursable services under the Medicare program, the pool of mental health professionals who can help address practitioner shortages in rural communities can expand.

D. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In the June 23, 2016 **Federal Register** (81 FR 41036), we published a final rule entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), that implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information with respect to the initial data reporting period.[140]

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage plan payments under Part C from the denominator of the Medicare revenues threshold calculation to broaden the types of laboratories qualifying as an applicable laboratory. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the original provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction could not be more than 10 percent per year. For the next 3 years after implementation (CY 2021 through CY 2023), section 216(a) of PAMA stated that the reduction could not be more than 15 percent per year. Under sections 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update were to occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019, through June 30, 2019, and the next data reporting period was originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502. Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are

[136] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1851736/.*

[137] *https://aspe.hhs.gov/sites/default/files/2021-07/rural-health-rr.pdf.*

[138] *https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1013&context=ruhrc_reports.*

[139] *https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1013&context=ruhrc_reports.*

[140] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website.[141]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Beginning in 2019, Congress passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS. First, section 105(a)(1) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019) (FCAA) amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year so that data reporting would be required during the period of January 1, 2021, through March 31, 2021, instead of January 1, 2020, through March 30, 2020. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applied to the data reporting period of January 1, 2021, through March 30, 2021, would be the period of January 1, 2019, through June 30, 2019, which was the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS at § 414.507(d) (81 FR 41036).

Subsequently, section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, March 27, 2020) further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022, through March 31, 2022. The CARES Act did not modify the data collection period that applied to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs would have been based on the data collection period of January 1, 2019 through June 30, 2019.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024 instead of CY 2023. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2022 through 2024, instead of CYs 2021 through 2023. In the CY 2021 PFS rulemaking (85 FR 50210 through 50211; 85 FR 84693 through 84694), in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021) made additional revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4(b) of PMAFSCA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2023, through March 31, 2023. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4 of PMAFSCA, section 1834A(a)(1)(B) of the Act provided that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2022; (ii) reporting is required during the period beginning January 1, 2023, and ending March 31, 2023; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4 of PMAFSCA did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2023, through March 31, 2023) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4 of PMAFSCA further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2025. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 and 2022 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 4(a) of PMAFSCA further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2023 through 2025, instead of CYs 2022 through 2024.

In the CY 2023 PFS rulemaking (87 FR 46068 through 46070; 87 FR 69741 through 69744, 70225), in accordance with section 4 of PMAFSCA, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we finalized revisions to § 414.502 to update the definitions of both the data collection period and data reporting period, specifying that for the data reporting period of January 1, 2023, through March 31, 2023, the data collection period is January 1, 2019, through June 30, 2019. We also revised

[141] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.*

§ 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 1, 2023. In addition, we finalized conforming changes to our requirements for the phase-in of payment reductions to reflect the PMAFSCA amendments. Specifically, we finalized revisions to § 414.507(d) to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

As a result of the statutory revisions under the FCAA, CARES Act, and PMAFSCA, there have only been two data collection periods for CDLTs that are not ADLTs to date. The first data collection period for these tests occurred from January 1, 2016, through June 30, 2016, and the second occurred from January 1, 2019, through June 30, 2019. Thus far, there has been only one data reporting period for these tests, which took place from January 1, 2017, through March 31, 2017. We have established CLFS payment rates for these tests using the methodology established in PAMA only one time, effective January 1, 2018, based on the applicable information collected by applicable laboratories during the 2016 data collection period and reported to CMS during the 2017 data reporting period.

Additionally, we have applied the phase-in of payment reductions for the first 3 years of PAMA implementation, CY 2018 through CY 2020, whereby reduction of payment rates could not be more than 10 percent per year as compared to the amount established the prior year. However, the phase-in of payment reductions set forth in PAMA for years 4 through 6 of PAMA implementation, whereby payment cannot exceed 15 percent per year as compared to the amount established the prior year, has not yet occurred.

4. Additional Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 4114 of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, enacted December 29th, 2022) made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4114(b) of the CAA, 2023 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one year, so that data reporting would be required during the period of January 1, 2024, through March 31, 2024, instead of the data reporting period of January 1, 2023 through March 31, 2023 established under the PMAFSCA. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4114(b) of the CAA, 2023, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2023; (ii) reporting is required during the period beginning January 1, 2024, and ending March 31, 2024; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4114 of the CAA, 2023 does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2024, through March 31, 2024) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4114(a) of the CAA, 2023 further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2026. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. Section 4114(a) of the CAA, 2023 further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2024 through 2026.

5. Proposed Conforming Regulatory Changes

In accordance with section 4114 of the CAA, 2023, we are proposing to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are proposing to revise § 414.502 to update the definitions of both the ''data collection period'' and ''data reporting period,'' specifying that for the data reporting period of January 1, 2024, through March 31, 2024, the data collection period is January 1, 2019, through June 30, 2019. We are also proposing to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2024. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 4114(a) of the CAA, 2023. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2023, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2022, and for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We note that the CYs 2023 and 2024 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016, through June 30, 2016. Under current law, the CLFS payment rates for CY 2025 through CY 2027 will be based on applicable information collected during the data collection period of January 1, 2019, through June 30, 2019, and reported to CMS during the data reporting period of January 1, 2024, through March 31, 2024.

E. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners

Conditions of coverage for pulmonary rehabilitation (PR), cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) are codified at 42 CFR 410.47 and 410.49. We are proposing revisions to the PR and CR/ICR regulations to codify the statutory changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA of 2018) which permit other specific practitioners to supervise the items and services effective January 1, 2024.

1. Statutory Authority

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, July 15, 2008) (MIPPA) amended title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare part B, as well as new section 1861(fff) of the Act to provide coverage of PR under Medicare

part B. The statute specified certain conditions for coverage of these services and an effective date of January 1, 2010. Conditions of coverage for PR, CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in §§ 410.47 and 410.49 respectively through the CY 2010 PFS final rule with comment period (74 FR 61872 through 61886 and 62002 through 62003 (PR) 62004 through 62005 (CR/ICR)). Section 51008 of the BBA of 2018, entitled ''Allowing Physician Assistants, Nurse Practitioners, and Clinical Nurse Specialists to Supervise Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Programs,'' amended sections 1861(eee) and (fff) of the Act, effective January 1, 2024. The amendment directs us to add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS).

2. Background

Under § 410.47(b), Medicare part B covers PR for beneficiaries with moderate to very severe chronic obstructive pulmonary disease (COPD) (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease and allows additional medical indications to be established through a national coverage determination (NCD). We have not added additional medical indications for PR using the NCD process; however, we used notice and comment rulemaking through the CY 2022 PFS final rule (86 FR 64996) to establish coverage of PR for beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks. In the same final rule, we also updated language to improve consistency and accuracy across PR and CR/ICR conditions of coverage and removed a PR requirement for direct physician-patient contact.

Under § 410.49(b), Medicare part B covers CR and ICR for beneficiaries who have experienced one or more of the following: (1) an acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; (6) a heart or heart-lung transplant; (7) stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014, for cardiac rehabilitation and on or after February 9, 2018, for intensive cardiac rehabilitation; or (8) other cardiac conditions as specified through an NCD. The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

In 2014, we established coverage of CR through the NCD process (NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03) to beneficiaries with stable, chronic heart failure. Section 51004 of the BBA of 2018, amended section 1861(eee)(4)(B) of the Act to expand coverage of ICR to include patients with stable, chronic heart failure. Section 410.49 was updated to codify this expansion through the CY 2020 PFS final rule (84 FR 62897 through 62899 and 63188). The CY 2022 PFS final rule (86 FR 64996) updated language in § 410.49 to improve consistency and accuracy across PR and CR/ICR conditions of coverage.

3. Proposals for Implementation

Consistent with the amendments made by section 51008 of the BBA of 2018 to section 1861(eee) and (fff) of the Act, we propose additions and revisions to language in §§ 410.47 and 410.49 as described below.

a. Definitions

We are proposing to add a new term, nonphysician practitioner (NPP), to §§ 410.47(a) and 410.49(a), which would be defined as a PA, NP, CNS as those terms are defined in section 1861(aa)(5)(A) of the Act.

We are proposing to amend the term supervising physician at §§ 410.47(a) and 410.49(a) to supervising practitioner and amend the definition to mean a physician or NPP.

Finally, we are proposing to amend the definition for pulmonary rehabilitation at § 410.47(a) and the definitions for cardiac rehabilitation and intensive cardiac rehabilitation (ICR) program at § 410.49(a) to specify that these are physician- or NPP-supervised programs.

b. Setting

We are proposing to amend § 410.47(b)(3)(ii)(A) and § 410.49(b)(3)(ii) to specify that all settings must have a physician or NPP immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the programs.

c. Supervising Practitioner Standards

We are proposing to amend language at §§ 410.47(d) and 410.49(e) by specifying that these sections include supervising practitioner standards, rather than just supervising physician standards. We are also removing the third standard in each section (§§ 410.47(d)(3) and 410.49(e)(3)) because specifying that a physician or NPP is licensed to practice medicine in the state where a PR/CR/ICR program is offered, or any corresponding reference to a NPP being licensed or authorized to practice, is redundant to the definition for each practitioner type in the Act. Since the physicians and NPPs that may supervise PR/CR/ICR are defined at §§ 410.47(a) and 410.49(a) by cross-reference to the Act, we believe repeating part of that definition in these sections is unnecessary.

4. Summary

We are proposing additions and revisions that are necessary to implement the amendments to section 1861(eee) and (fff) of the Act set forth in section 51008 of the BBA of 2018, which expand the types of practitioners that may supervise PR, CR and ICR. This includes changes to the regulatory language in the definitions, settings and supervising practitioner standards sections under §§ 410.47 and 410.49. We believe these proposed amendments to §§ 410.47 and 410.49 would serve to implement the provisions in the BBA of 2018 regarding the types of practitioners that may supervise PR, CR and ICR beginning January 1, 2024. All other provisions of these regulations would remain unchanged.

F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) established a new Medicare Part B benefit for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We also

established in the CY 2020 PFS final rule new codes and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. In the CY 2021 PFS final rule (85 FR 84683 through 84692), we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone. In the CY 2022 PFS final rule (86 FR 65340 and 65341), we established a new add-on code and payment for a higher dose of nasal naloxone. We also revised paragraphs (iii) and (iv) in the definition of ''Opioid disorder treatment service'' at § 410.67(b) to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the public health emergency (PHE) for COVID–19 in cases where audio/video communication technology is not available to the beneficiary, provided all other applicable requirements are met (86 FR 65342).

More recently, CMS made further modifications and expansions to covered services for the treatment of OUD by OTPs in the CY 2023 PFS final rule (87 FR 69768 through 69777). Specifically, we revised our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone by using the payment amount for methadone for CY 2021 updated by the PPI for Pharmaceuticals for Human Use (Prescription) to better reflect the changes in methadone costs for OTPs over time. Additionally, we finalized a modification to the payment rate for individual therapy in the non-drug component of the bundled payment for an episode of care to base the payment rate on the rate for longer therapy sessions that better account for the greater severity of needs for patients with an OUD and receiving treatment in the OTP setting. Moreover, for the purposes of the geographic adjustment, we clarified that services furnished via OTP mobile units will be treated as if the services were furnished in the physical location of the OTP for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) guidance. We believe that this policy enables OTPs to better serve Medicare beneficiaries living in underserved areas by providing access to many of the same OUD treatment services offered at the brick and mortar location of the OTP. We are continuing to monitor utilization of OUD treatment services furnished by OTPs to ensure that Medicare beneficiaries have appropriate access to care. For CY 2024, we are proposing several modifications to the policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Additional Flexibilities for Periodic Assessments Furnished via Audio-Only Telecommunications

We have finalized several flexibilities for OTPs regarding the use of telecommunications, both during the PHE for COVID–19 and outside of the PHE. In the CY 2020 PFS final rule, we finalized a policy allowing OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology. In the IFC entitled ''Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19258), we revised paragraphs (iii) and (iv) in the definition of opioid use disorder treatment service at § 410.67(b) on an interim final basis to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 if beneficiaries do not have access to two-way audio-video communications technology, provided all other applicable requirements are met. In the CY 2022 PFS final rule (86 FR 65341 through 65343), we finalized that after the conclusion of the PHE for COVID–19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when audio and video communication technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. More recently in the CY 2023 PFS final rule (87 FR 69775 through 69777), we further extended telecommunication flexibilities for the initiation of treatment with buprenorphine outside of the COVID–19 PHE. Specifically, we allowed the OTP intake add-on code to be furnished via two-way, audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, provided all other applicable requirements are met.

In the IFC entitled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which appeared in the May 8, 2020 **Federal Register** (85 FR 27558), we revised paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video telecommunication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. In the CY 2021 PFS final rule (85 FR 84690), we finalized our proposal to revise paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) to provide that periodic assessments (HCPCS code G2077) must be furnished during a face-to-face encounter, which includes services furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable

requirements are met, on a permanent basis.

Furthermore, in the CY 2023 PFS proposed rule (87 FR 46093), we sought comment on whether we should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID–19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone. In response, several commenters advocated for CMS to continue to allow periodic assessments to be furnished audio-only when video is not available after the end of the PHE. Commenters highlighted that making audio-only flexibilities permanent would further promote equity for individuals who are economically disadvantaged, live in rural areas, are racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video capability. Additionally, a commenter cited a 2020 HHS Issue Brief indicating higher utilization of audio-only visits for older adults. Specifically, evidence suggests that the proportion of telephonic audio-only visits increases with the age of the patient, with ''17 percent of visits delivered via audio-only interaction for patients 41–60 years of age, 30 percent for patients 61–80 years of age, and 47 percent of visits for patients over 81.'' [142] One commenter stated that periodic assessments are no less complex than intake/initial assessments, and thus are equally appropriate for audio-video and audio-only care. Lastly, several commenters expressed support for the use of telecommunications in circumstances when the provider and patient have together determined that the patient would individually benefit from telehealth services and a high quality of care is maintained. They encouraged CMS to expand flexibilities to furnish substance use disorder (SUD) services via telecommunications to allow providers and patients to decide collaboratively the best modality for individualized care. After considering these comments, CMS determined that it would be appropriate to allow periodic assessments to be furnished audio-only when video is not available through the end of CY 2023, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and, in a manner consistent with all applicable requirements. We stated our belief that this modification would allow continued beneficiary access to these services for the duration of CY 2023 in the event the PHE terminated before the end of 2023 and that it would also grant additional time for CMS to further consider telecommunication flexibilities associated with periodic assessments. Accordingly, we revised the requirements related to the periodic assessment services in paragraph (vii) in the definition of ''Opioid use disorder treatment services'' at § 410.67(b) of the regulations to reflect these changes.

Section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extended the telehealth flexibilities enacted in the Consolidated Appropriations Act of 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022). Specifically, it amended sections 1834(m), 1834(o), and 1834(y) of the Act to delay the requirement for an in-person visit prior to furnishing certain mental health services via telecommunications technology by physicians and other practitioners, Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs) until dates of service on or after January 1, 2025 if the COVID–19 PHE ends prior to that date. Additionally, it extended the flexibilities available during the PHE that allow for certain Medicare telehealth services defined in section 1834(m)(4)(F)(i) of the Act to be furnished via an audio-only telecommunications system through December 31, 2024 if the PHE for COVID–19 ends prior to that date. The PHE for COVID–19, which was declared under section 319 of the Public Health Service Act, expired at the end of the day on May 11, 2023, so the aforementioned flexibilities will be extended through the end of CY 2024 or CY 2025, as applicable.

To better align coverage for periodic assessments furnished by OTPs with the telehealth flexibilities described in section 4113 of the CAA, 2023, we are proposing to extend the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024. Under this proposal, we would allow periodic assessments to be furnished audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished and all other applicable requirements are met. We believe extending this flexibility would promote continued beneficiary access to these services following the end of the PHE and for the duration of CY 2024. During the COVID–19 pandemic, substance use disorder treatment facilities increased telemedicine offerings by 143 percent, and as of 2021, almost 60 percent of SUD treatment facilities offer telehealth.[143] Notably, telephone-based (that is, audio-only) therapy and recovery support services provided by SUD programs have been found to be one of the most common modes of telehealth for treatment of opioid use disorder.[144] Therefore, extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE. Additionally, evidence has shown that Medicare beneficiaries who are older than 65 years-old, racial/ethnic minorities, dual-enrollees, or living in rural areas, or who experience low broadband access, low-income, and/or not speaking English as their primary language, are more likely to be offered and use audio-only telemedicine services than audio-video services.[145] Other evidence also suggests that while Tribal populations, including American Indian and Alaska Natives, have the highest rates of OUD prevalence among Medicare beneficiaries, one-third of these populations do not have adequate access to high-speed broadband and continue to rely on audio-only visits.[146] Therefore, minimizing disruptions to care for beneficiaries currently receiving audio-only periodic assessments may further promote health equity and minimize disparities in access to care. Lastly, extending these flexibilities another year will allow CMS time to further consider this issue, including whether periodic assessments should continue to be furnished using audio-only communication technology following the end of CY 2024 for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs.

Accordingly, we are proposing to revise paragraph (vii) of the definition of

[142] HHS ASPE Issue Brief: Medicare beneficiary use of telehealth visits: Early Data from the Start of the COVID–19 Pandemic (July 27, 2020). *https://aspe.hhs.gov/reports/medicare-beneficiary-use-telehealth-visits-early-data-start-covid-19-pandemic.*

[143] *https://pubmed.ncbi.nlm.nih.gov/34407631/.*

[144] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8250742/.*

[145] *https://pubmed.ncbi.nlm.nih.gov/33471458/*; *https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/*; *https://journals.lww.com/lww-medicalcare/Fulltext/2021/11000/Disparities_in_Audio_only_Telemedicine_Use_Among.10.aspx.*

[146] *https://docs.fcc.gov/public/attachments/FCC-20-50A1.pdf*; *https://www.cms.gov/files/document/aian-telehealthwebinar.pdf*; *https://www.sciencedirect.com/science/article/pii/S0749379721000921?via%3Dihub.*

''Opioid treatment services'' at § 410.67(b) of the regulations to state that through the end of CY 2024, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

3. Intensive Outpatient Program (IOP) Services Provided by OTPs

In the CY 2023 PFS proposed rule, we solicited comments on intensive outpatient mental health treatment (87 FR 45943 through 45944). Commenters emphasized the importance of ensuring access to intensive outpatient program (IOP) services in OTP settings and that these services are valuable to those with SUDs (for example, OUD), including individuals who cannot stabilize at a lower level of care or require more care than can be provided in office settings and individuals who have stabilized biomedical conditions and the need for close monitoring but no longer require a higher level of care for SUD treatment, such as partial hospitalization or inpatient care.

Please see the CY 2024 Outpatient Prospective Payment System proposed rule for the full policy discussion and additional details regarding Medicare payment for IOP services provided by OTPs.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Medicare Shared Savings Program (Shared Savings Program) by forming or joining an accountable care organization (ACO) and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare fee-for-service (FFS) beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending.

As of January 1, 2023, 10.9 million people with Medicare receive care from one of the 573,126 health care providers in the 456 ACOs participating in the Shared Savings Program, the largest value-based care program in the country.[147] While the Shared Savings Program experienced a decrease in the number of ACOs and assigned beneficiaries for 2023, the policies finalized in the CY 2023 PFS final rule (87 FR 69777 through 69968) are expected to grow participation in the program for 2024 and beyond, when many of the new policies are set to go into effect. These policies are expected to drive growth in participation, particularly in rural and underserved areas, promote equity, advance alignment across accountable care initiatives, and increase the number of beneficiaries assigned to ACOs participating in the program by up to four million over the next several years.[148] Accordingly, we expect these recently finalized changes will support CMS in achieving its goal of having 100 percent of people with Original Medicare in a care relationship with accountability for quality and total cost of care by 2030.[149]

Section III.G. of this proposed rule addresses changes to the Shared Savings Program regulations to further advance Medicare's overall value-based care strategy of growth, alignment, and equity, and to respond to concerns raised by ACOs and other interested parties. We propose changes to the quality performance standard and reporting requirements under the Alternative Payment Model (APM) Performance Pathway (APP) within the Quality Payment Program (QPP) that would continue to move ACOs toward digital measurement of quality and align with the QPP. Further, the policy proposals would add a third step to the step-wise beneficiary assignment methodology under which we would use an expanded period of time to identify whether a beneficiary has met the requirement for having received a primary care service from a physician who is an ACO professional in the ACO to allow additional beneficiaries to be eligible for assignment, as well as to propose related changes to how we identify assignable beneficiaries used in certain Shared Savings Program calculations. Additionally, we are proposing updates to the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines. We also propose refinements to the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years to cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth; apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year; further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries; and specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations. We are also proposing to refine our policies for the newly established advance investment payments (AIP) and make updates to other programmatic areas including the program's eligibility requirements and make timely technical changes to the regulations for clarity and consistency. Lastly, we seek comment on potential future developments to Shared Savings Program policies, including with respect to incorporating a new track that would offer a higher level of risk and potential reward than currently available under the ENHANCED track, refining the three-way blended benchmark update factor and the prior savings adjustment, and promoting ACO and community-based organization (CBO) collaboration.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and

[147] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2023, available at *https://www.cms.gov/files/document/2023-shared-savings-program-fast-facts.pdf*.

[148] See CMS Press Release, ''CMS Announces Increase in 2023 in Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship'', January 17, 2023, available at *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable*.

[149] Ibid. See also, Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444*. CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper* (Innovation Center Strategic Objective 1: Drive Accountable Care, pages 13–17).

Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 of the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255, December 13, 2016). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'')). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction that prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared

losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2020 PFS proposed rule (84 FR 40705), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), and the CY 2023 PFS final rule (87 FR 69779 and 69780). In the CY 2023 PFS final rule (87 FR 69777 through 69968), we finalized changes to Shared Savings Program policies, including to: provide advance shared savings payments in the form of advance investment payments to certain new, low revenue ACOs that can be used to support their participation in the Shared Savings Program; provide greater flexibility in the progression to performance-based risk; establish a health equity adjustment to an ACO's Merit-based Incentive Payment System (MIPS) quality performance category score used to determine shared savings and losses to recognize high quality performance by ACOs serving a higher proportion of underserved populations; incorporate a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs, and revise the approach for determining shared losses for ENHANCED track ACOs; modify the benchmarking methodology to strengthen financial incentives for long term participation by reducing the impact of ACOs' performance and market penetration on their benchmarks, and to support the business case for ACOs serving high risk and high dually eligible populations to participate, as well as mitigate bias in regional expenditure calculations for ACOs electing prospective assignment; expand opportunities for certain low revenue ACOs participating in the BASIC track to share in savings; make changes to policies within other programmatic areas, including the program's beneficiary assignment methodology, requirements related to marketing material review and beneficiary notifications, the SNF 3-day rule waiver application, and data sharing requirements.

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Proposals

In sections III.G.2. through III.G.7. of this proposed rule, we propose modifications to the Shared Savings Program's policies, and describe comment solicitations. As a general summary, we are proposing the following changes to Shared Savings Program policies to:

- Revise the quality reporting and the quality performance requirements (section III.G.2. of this proposed rule), including the following:

++ Allow Shared Savings Program ACOs the option to report quality measures under the APP on only their Medicare beneficiaries through Medicare CQMs (section III.G.2.b. of this proposed rule).

++ Update the APP measure set for Shared Savings Program ACOs (section III.G.2.c. of this proposed rule).

++ Revise the calculation of the health equity adjustment underserved multiplier (section III.G.2.d. of this proposed rule).

++ Use historical data to establish the 40th percentile MIPS Quality performance category score used for the quality performance standard (section III.G.2.e. of this proposed rule).

++ Apply a Shared Savings Program scoring policy for suppressed APP measures (section III.G.2.f. of this proposed rule).

++ Require Spanish language administration of the CAHPS for MIPS survey (section III.G.2.g. of this proposed rule).

++ Align CEHRT requirements for Shared Savings Program ACOs with MIPS (section III.G.2.h. of this proposed rule).

++ Solicit comments on MIPS Value Pathway reporting for specialists in Shared Savings Program ACOs (section III.G.2.i. of this proposed rule).

++ Revise the requirement to meet the case minimum requirement for quality performance standard determinations (section III.G.2.j. of this proposed rule).

- Revise the policies for determining beneficiary assignment (section III.G.3 of this proposed rule).

++ Modify the step-wise beneficiary assignment methodology and approach to identifying the assignable beneficiary population (section III.G.3.a of this proposed rule).

++ Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.G.3.b of this proposed rule).

- Revise the policies on the Shared Savings Program's benchmarking methodology (section III.G.4 of this proposed rule).

++ Modify the calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth (section III.G.4.b of this proposed rule).

++ Further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries (section III.G.4.c of this proposed rule).

++ Specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year (section III.G.4.d of this proposed rule).

++ Specify use of the CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating prospective HCC risk scores for Medicare FFS beneficiaries for the performance year, and for each benchmark year of the ACO's agreement period (section III.G.4.e. of this proposed rule).

- Refine AIP policies, including the following (section III.G.5 of this proposed rule):

++ Modify AIP eligibility requirements to allow an ACO to elect to advance to a two-sided model level of the BASIC track's glide path beginning with the third performance year of the 5-year agreement period in which the ACO receives advance investment payments.

++ Modify AIP recoupment and recovery polices to forgo immediate collection of advance investment payments from an ACO that terminates its participation agreement early in order to early renew under a new participation agreement to continue their participation in the Shared Savings Program.

++ Modify termination policies to specify that CMS would immediately terminate advance investment payments

to an ACO for future quarters if the ACO voluntarily terminates from the Shared Savings Program.

++ Modify ACO reporting requirements to require ACOs to submit spend plan updates to CMS in addition to publicly reporting spend plan updates.

++ Modify AIP requirements to permit ACOs to seek reconsideration review of all quarterly payment calculations.

• Update Shared Savings Program eligibility requirements, including the following (section III.G.6 of this proposed rule):

++ Remove the option for ACOs to request an exception to the shared governance requirement that 75 percent control of an ACO's governing body must be held by ACO participants.

++ Codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was included on a participant list used in financial reconciliation for a performance year under performance-based risk during the five most recent performance years.

• Make technical changes to references in Shared Savings Program regulations (section III.G.7 of this proposed rule), including to update assignment selection references to either § 425.226(a)(1) or § 425.400(a)(4)(ii) in subpart G of the regulations, correct typographical errors in the definitions in § 425.20, and update certain terminology used in § 425.702.

In addition, we are soliciting comment on potential future developments to Shared Savings Program policies (section III.G.8. of this proposed rule), including: incorporating a track with higher risk and potential reward than the ENHANCED track; modifying the amount of the prior savings adjustment through potential changes to the 50 percent scaling factor used in determining the adjustment, as well as considerations for potential modifications to the positive regional adjustment to reduce the possibility of inflating the benchmark; potential refinements to the ACPT and the three-way blended benchmark update factor over time to further mitigate potential ratchet effects within the update factor; and policies to promote ACO and CBO collaboration.

In combination, the Shared Savings Program proposals are anticipated to improve the incentive for ACOs to sustainably participate and earn shared savings in the program. On net, total program spending is estimated to decrease by $330 million over the 10-year period 2024 through 2033. These changes are anticipated to support the goals outlined in the CY 2023 PFS final rule for growing the program with a particular focus on including underserved beneficiaries.

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: the proposed modifications to the calculation of regional component of the three-way blended update factor to cap regional service area risk score growth for symmetry with the ACO risk score growth cap, as described in section III.G.4.b of this proposed rule and the refinements to AIP policies as described in section III.G.5. of this proposed rule. Further, certain existing policies adopted under the authority of section 1899(i)(3) of the Act that depend on use of the assigned population and assignable beneficiary populations would be affected by the proposed addition of a new third step of the beneficiary assignment methodology and the proposed revisions to the definition of assignable beneficiary described in section III.G.3. of this proposed rule, including the following: the amount of advance investment payments; factors used in determining shared losses for ACOs under two-sided models (including calculation of the variable MSR/MLR based on the ACO's number of assigned beneficiaries, and the applicability of the extreme and uncontrollable circumstances policy for mitigating shared losses for two-sided model ACOs); and calculation of the ACPT, regional and national components of the three-way blended benchmark update factor. As described in the Regulatory Impact Analysis in section VII. and elsewhere in this proposed rule, these proposed changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

2. Quality Performance Standard and Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, and 2023 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71269, 81 FR 80484 through 80488, 83 FR 59707 through 59715, 87 FR 69860 through 69763, respectively).

b. Proposal for Shared Savings Program ACOs To Report Medicare CQMs

(1) Background

In the CY 2021 PFS final rule, CMS finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for performance year 2021 and subsequent performance years (85 FR 84720). For performance year 2021 and subsequent years, ACOs are required to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). Pursuant to policies

finalized under the CY 2022 and CY 2023 PFS (86 FR 65685; 87 FR 69858), to meet the quality performance standard under the Shared Savings Program through performance year 2024, ACOs must report the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey. In performance year 2025 and subsequent performance years, ACOs must report the three eCQMs/MIPS CQMs and the CAHPS for MIPS survey.

Since the CY 2021 PFS final rule was issued, interested parties have continued to express concerns about requiring ACOs to report all payer/all patient eCQMs/MIPS CQMs via the APP due to the cost of purchasing and implementing a system wide infrastructure to aggregate data from multiple ACO participant TINs and varying EHR systems (86 FR 65257). In the CY 2022 PFS, commenters supported our acknowledgement of the complexity of the transition to all payer/all patient eCQM/MIPS CQMs (86 FR 65259). Additionally, one commenter questioned how data completeness standards could be met, given the issues of de-duplication and patients adding or moving insurance coverage (87 FR 65260). In public comment to the CY 2023 PFS proposed rule, some commenters expressed multiple concerns regarding the requirement to report all payer/all patient eCQMs/MIPS CQMS beginning in performance year 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and deduplication issues, and interoperability issues among different EHRs (87 FR 69837). In the CY 2023 PFS final rule, we explained these comments went beyond the scope of our proposals. These comment letters included details of the commenters' concerns. Specifically, some commenters, which included ACOs, noted the financial burden of aggregating, deduplicating, and exporting eCQM data across multiple TINs and EHRs. Commenters, including ACOs, expressed concerns that the requirement to report all payer measures ties performance to patients that the ACO does not actively manage, increases the difficulty of meeting data completeness, and may negatively impact an ACO's performance by including patients seen by specialists. We also acknowledged that as the transition to reporting all-payer eCQMs/MIPS CQMs continues, the health equity adjustment which we finalized in the CY 2023 PFS final rule (87 FR 69842) will support ACOs that may experience challenges with the new quality reporting requirement and will provide an incentive for ACOs to serve underserved populations during the transition to reporting eCQMs/MIPS CQMs. In the CY 2023 PFS final rule, we stated that we are continuing to monitor the impact of these policies as we gain more experience with ACOs reporting all payer/all patient eCQMs/MIPS CQMs and, further, that we are exploring how to address some of the concerns related to data aggregation and the all payer requirement and may revisit these and related issues in future rulemaking based on lessons learned (87 FR 69833).

Consistent with our goal to support ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs, in the CY 2023 final rule we extended the eCQM/MIPS CQM reporting incentive through PY 2024 to provide an incentive to ACOs to report the eCQMs/MIPS CQMs, while allowing them time to gauge their performance on the eCQMs/MIPS CQMs before full reporting of these measures is required beginning in performance year 2025 (87 FR 69835). Building on our goal to provide technical support to ACOs and to help ACOs build the skills necessary to aggregate and match patient data to report all payer/all patient eCQMs/MIPS CQMS, in December 2022, we hosted a webinar to support ACOs in the transition to reporting all payer/all patient eCQMs/MIPS CQMs and released a guidance document on the topic. Resources from the ''Reporting MIPS CQMs and eCQMs in the APM Performance Pathway'' webinar are available at *https://qpp.cms.gov/resources/webinars.* The guidance document, entitled ''Medicare Shared Savings Program: Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP)'' is available in the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2179/APP%20Guidance%20Document%20for%20ACOs.pdf.* We are committed to continuing to support ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs and in the transition to digital quality measurement reporting.

(2) Reporting the Medicare CQMs

In light of the concerns raised by ACOs and other interested parties and our commitment to supporting ACOs in the transition to digital quality measure reporting, for performance year 2024 and subsequent performance years as determined by CMS, we are proposing in section IV.A.4.f.(1)(b) of this proposed rule to establish the Medicare CQMs for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP. Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that exist within the all payer/all patient MIPS CQM Specifications and tethering that population to claims encounters with ACO professionals with specialties used in assignment. Specifically, we believe that Medicare CQMs would address the concern raised by ACOs that—for ACOs with a higher proportion of specialty practices and/or multiple EHR systems—the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the ACO. Further, we believe that ACOs, particularly ACOs with a higher proportion of specialty practices and/or multiple EHRs, would be able utilize Medicare Part A and B claims data to help identify the ACO's eligible population and to validate the ACO's patient matching and deduplication efforts. For these reasons, we believe that it is appropriate to establish Medicare CQMs as a new collection type for Shared Savings Program ACOs only.

We recognize that Medicare CQMs might not be the suitable collection type for some ACOs, particularly ACOs with a single-EHR platform, a high proportion of primary care practices, and/or ACOs composed of participants with experience reporting all payer/all patient measures in traditional MIPS. We encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure. In addition to this proposal to report quality data utilizing the Medicare CQMs collection type, in performance year 2024, ACOs would have the option to report quality data utilizing the CMS Web Interface measures, eCQMs, and/or MIPS CQMs collection types. Under this proposal, in performance year 2025 and subsequent performance years as determined by CMS, ACOs would have the option to

report quality data utilizing the eCQMs, MIPS CQMs, and/or Medicare CQMs collection types.

Our long-term goal continues to be to support ACOs in the adoption of all payer/all patient measures. We would monitor the reporting of quality data utilizing the Medicare CQMs collection type. For example, one indicator to evaluate Medicare CQMs would be to assess if there are any Medicare CQMs topped out as described at § 414.1380(b)(1)(iv). Therefore, in the 4th year the measure could be removed and would no longer be available for reporting during the performance period (83 FR 59761). Once the measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors (83 FR 59763). Separately, we may specify higher standards, new measures, or both—up to and including proposing to sunset the Medicare CQM collection type in future rulemaking—to ensure that Medicare CQMs conform to the intent of section 1899(b)(3)(C) of the Act and the priorities established in the CMS National Quality Strategy.

We also remain steadfast in our commitment to support providers in the transition from traditional MIPS to APMs and Advanced APMs. As mentioned above, we acknowledge that Medicare CQMs may not be the preferred collection type for all ACOs. ACOs that are composed of participants with experience reporting all payer/all patient measures in traditional MIPS would continue to have the option to report all payer/all patient measures under this proposal. In supporting providers in the transition from traditional MIPS to APMs and Advanced APMs we also recognize the corresponding need to support ACOs in the transition to all payer/all patient reporting. In addition to the technical support we would continue to provide ACOs, we believe that the Medicare CQM collection type would aid some ACOs in the transition to all payer/all patient measures by allowing ACOs to focus patient matching and data aggregation efforts on ACO professionals with specialties used in assignment while the ACO builds the infrastructure necessary to report on a broader eligible population.

To facilitate the reporting of Medicare CQMs, we are proposing to amend the definition of ''Collection Type'' in section IV.A.4.f.(1)(b) of this proposed rule to include the Medicare CQM as an available collection type in MIPS for ACOs that participate in the Shared Savings Program. We note that the Medicare CQMs collection type would serve as a transition collection type and be available as determined by CMS. Additionally, we are proposing to establish data submission and completeness criteria pertaining to the Medicare CQMs for the MIPS quality performance category as discussed in sections IV.A.4.f.(1)(c)(i) and IV.A.4.f.(1)(d)(ii) of this proposed rule.

A Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) is essentially a MIPS CQM reported by an ACO under the APP on only the ACO's Medicare fee-for-service beneficiaries, instead of its all payer/all patient population. We are proposing to define a beneficiary eligible for Medicare CQM at § 425.20 as a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs) who is either of the following:

- A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

++ Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

++ Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a PA, NP, or CNS.

- A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

While this definition refers to beneficiaries that have been assigned to an ACO, it nonetheless differs from our basic assignment methodology described under subpart E and from the concept of assignable beneficiary defined at § 425.20. Specifically, the use of the terms of ''claim'' (instead of primary care services) and ''measurement period'' (instead of assignment window) in the definition are synchronous with the application of all payer/all patient MIPS CQM Specifications in reporting Medicare CQMs. For example, we define primary care services as the set of services identified by the HCPCS and revenue center codes designated under § 425.400(c). Each all payer/all patient MIPS CQM Specification identifies eligible encounters that, in part, identify patients that should be included in the measure's eligible population.

Our proposed definition for beneficiary eligible for Medicare CQMs is intended to create alignment with the all payer/all patient MIPS CQM Specifications. The HCPCS and revenue center codes designated under § 425.400(c) as primary care services for purposes of assignment under the Shared Savings Program only partially over-lap with the codes designated as eligible encounters used to identify the eligible population in all payer/all patient MIPS CQM Specifications. Applying primary care service codes or deferring to the basic assignment methodology under subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of limiting the codes used to identify eligible encounters in the Medicare CQM Specification to only the codes that overlap with primary care services. Similarly, we define the assignment window as the 12-month period used to assign beneficiaries to the ACO. In a manner that is identical to the all payer/all patient MIPS CQM Specifications, the Medicare CQM Specifications would identify the measurement period applicable to each measure. Applying the 12-month period used in assignment or deferring to the basic assignment methodology under Subpart E to identify the beneficiaries eligible for Medicare CQMs would have the unintended result of reducing the beneficiaries eligible for Medicare CQMs to only patients that had an eligible encounter during the overlap of the assignment window as defined at § 425.20 and the measurement period as defined in the Medicare CQM Specifications.

In section IV.A.4.f.(1)(d)(ii)of this proposed rule, we are proposing to establish the data completeness criteria threshold for the Medicare CQM collection type, in which a Shared Savings Program ACO that meets the reporting requirements under the APP would submit quality measure data for Medicare CQMs on the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed at § 425.20, who meet the measure's denominator criteria. In section IV.A.4.f.(1)(d)(ii) of this proposed rule, we are proposing the following data completeness criteria thresholds for Medicare CQMs:

- At least 75 percent for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years.
- At least 80 percent for the CY 2027 performance period/2029 MIPS payment year.

With the Medicare CQMs collection type serving as a transition collection type under the APP and would be available as determined by CMS, we are proposing to establish the aforementioned data completeness criteria thresholds in advance of the applicable performance periods. We recognize that it is advantageous to delineate the expectations for ACOs as they prepare to meet the quality reporting requirements for the Medicare CQMs collection type under the APP. We will assess the availability of the Medicare CQM as a collection type under the APP during the initial years of implementation and determine the timeframe to sunset the Medicare CQM as a collection type in future rulemaking.

An ACO that reports Medicare CQMs in an applicable performance year would aggregate patient data for beneficiaries who are eligible for Medicare CQMs, as proposed at § 425.20, across all ACO participants. The ACO would then match the aggregated patient data with each Medicare CQM Specification to identify the eligible population for each measure. The ACO's aggregated ACO submission must account for 100 percent of the eligible and matched patient population across all ACO participants. Data completeness is calculated based on submitted data. We believe that the proposal to establish the Medicare CQM collection type would address the concerns from ACOs regarding the capability of meeting the data completeness requirement for all payer data. Specifically, our proposal to define Beneficiaries eligible for Medicare CQMs aims to focus ACOs' reporting efforts on beneficiaries with an encounter with an ACO professional with a specialty used in assignment and thereby reduce the potential for missing or un-matched patient data. It is important to note that ACOs that include or are composed solely of FQHCs or RHCs must report quality data on behalf of the FQHCs or RHCs that participate in the ACO. To clarify, while FQHCs and RHCs that provide services that are billed exclusively under FQHC or RHC payment methodologies are exempt from reporting traditional MIPS, FQHCs and RHCs that participate in APMs, such as the Shared Savings Program, are considered APM Entity groups described at § 414.1370.

To facilitate population-based activities related to improving health through quality measurement of Medicare CQMs and to aid ACOs in the process of patient matching and data aggregation necessary to report Medicare CQMs, we would provide ACOs a list of beneficiaries who are eligible for Medicare CQMs within the ACO. As set forth in our regulations at § 425.702, we share certain aggregate reports with ACOs under specific conditions, and this information includes demographic data that represents the minimum data necessary for ACOs to conduct health care operations work, which includes demographic and diagnostic information necessary to report quality data. We anticipate the list of beneficiaries eligible for Medicare CQMs to be shared once annually, at the beginning of the quality data submission period. Since we would not have full run-out on performance year claims data prior to the start of the quality data submission period, the list of beneficiaries eligible for Medicare CQMs would not be a complete list of beneficiaries that should be included on an ACO's Medicare CQMs reporting. ACOs would have to ensure that all beneficiaries that meet the applicable Medicare CQM Specification and also meet the definition of a beneficiary eligible for Medicare CQMs proposed under § 425.20 are included in the ACO's eligible population/denominator for reporting each Medicare CQM. We are proposing to add new paragraph (c)(1)(iii) to § 425.702 as follows:

For performance year 2024 and subsequent performance years, at the beginning of the quality submission period, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

- The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:
  - ++ Beneficiary name.
  - ++ Date of birth.
  - ++ Beneficiary identifier.
  - ++ Sex.
- Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:
  - ++ Demographic data such as enrollment status.
  - ++ Health status information such as risk profile and chronic condition subgroup.
  - ++ Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

The list of beneficiaries eligible for Medicare CQMs shared by CMS would aim to help ACOs aggregate, and match and deduplicate patient data. We anticipate including the minimum data necessary to facilitate the reporting of Medicare CQMs including beneficiary identifier, gender, date of birth and death (if applicable), chronic condition subgroup, and the NPIs of the top three frequented providers in the ACO. We propose to include health status information such as risk profile and chronic condition subgroup to the extent that such data would aid ACOs in identifying patients that meet the denominator criteria for the Medicare CQM Specifications. We would also provide technical assistance to ACOs when reporting the Medicare CQMs, including providing technical resource documents. Our proposal to create Medicare CQMs is intended to support ACOs through the transition to reporting the all payer/all patient eCQMs/MIPS CQMs and to facilitate quality assessment improvement activities (as described in the definition of health care operations at 45 CFR 164.501) since we would provide ACOs with a list of beneficiaries eligible for Medicare CQM reporting to aid in patient matching and data deduplication.

In the CY 2021 PFS final rule (85 FR 84733), we finalized the following 3 all payer/all patient eCQMs/MIPS CQMs under the APP for performance year 2021 and subsequent performance years:

- Quality ID#: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control;
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure.

In section IV.A.4. e. of this proposed rule, we are proposing to add these measures as Medicare CQMs to the APP measure set for Shared Savings Program ACOs beginning with performance year 2024 and subsequent performance years. ACOs may report the 3 Medicare CQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5).

As a result, in order to meet the Shared Savings Program reporting requirements:

• For performance year 2024, an ACO would be required to report the 10 measures under the CMS web interface measures, or the 3 eCQMs/MIPS CQMs/Medicare CQMs. In addition, an ACO would be required to administer the CAHPS for MIPS Survey, and CMS will calculate the two claims-based measures.

• For performance year 2025 and subsequent performance years, an ACO would be required to report the 3 eCQMs/MIPS CQMs/Medicare CQMs. In addition, an ACO would be required to administer the CAHPS for MIPS Survey, and CMS will calculate the two claims-based measures.

ACOs may still report via the APP using the all payer/all patient eCQM/MIPS CQM collection types and may report different collection types for each measure.

In conjunction with the proposed changes to § 425.512(a)(2), as described in section III.G.2.j. of this proposed rule, we propose to incorporate Medicare CQMs into the existing quality performance standard policies for new ACOs at § 425.512(a)(2)(i), (ii), and (iii). Accordingly, we propose that for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO reports data via the APP and meets MIPS data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), the ACO will meet the quality performance standard under the Shared Savings Program, if:

• For performance year 2024. The ACO reports the 10 CMS Web Interface measures or the 3 eCQMs/MIPS CQMs/Medicare CQMs, and administers a CAHPS for MIPS survey under the APP.

• For performance year 2025 and subsequent performance years. The ACO reports the 3 eCQMs/MIPS CQMs/Medicare CQMs and administers a CAHPS for MIPS survey under the APP.

Additionally, we propose to incorporate Medicare CQMs into the existing policies at § 425.512(a)(5)(iii) for when an ACO would not meet the quality performance standard or the alternative quality performance standard. Accordingly, we propose that an ACO would not meet the quality performance standard or the alternative quality performance standard if:

• For performance year 2024, if an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP.

• For performance year 2025 and subsequent performance years, if an ACO (1) does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP.

We are not proposing to add Medicare CQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(*2*) for performance year 2024. The eCQM/MIPS CQM reporting incentive intends to provide an incentive to ACOs to report the all payer/all patient eCQMs/MIPS CQMs while allowing them time to gauge their performance on the all payer/all patient eCQMs/MIPS CQMs before full reporting of these measures is required beginning in performance year 2025.

Under the goals of the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measure across CMS quality programs for the adult and pediatric populations. This ''Universal Foundation'' of quality measure will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. Following in the proposals under MIPS, we intend to propose future policies aligning the APP measure set for Sharing Savings Program ACOs with the quality measures under the ''Universal Foundation'' beginning in performance year 2025. These Universal Foundation measures are proposed to be adopted into the existing the Value in Primary Care MVP as discussed in Table B.11 of Appendix 3: MVP Inventory to this proposed rule. By creating alignment with the Universal Foundation in the Value in Primary Care MVP and the APP measure set by 2025, primary care clinicians would develop familiarity with the same quality measures that are reported in the APP while in MIPS. We expect this alignment would reduce the barriers to participation in the Shared Savings Program.

(3) Benchmarking Policy for Medicare CQMs

As the Shared Savings Program adopted the APP (see, for example, § 425.512(a)(3)(i)), benchmarks for quality measures used by the program are those established under the MIPS policies at § 414.1380(b)(1)(ii). We propose that new benchmarks for scoring ACOs on the Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking policies. As historical Medicare CQM data would not be available at the time this proposal is finalized (if this proposal is finalized), we propose for performance year 2024 and 2025 to score Medicare CQMs using performance period benchmarks. Similarly, as quality performance data are submitted via Medicare CQM and baseline period data become available to establish historical benchmarks, we propose for performance year 2026 and for subsequent performance years to transition to using historical benchmarks for Medicare CQMs when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii).

(4) Expanding the Health Equity Adjustment to Medicare CQMs

In the CY 2023 PFS final rule (87 FR 69838 through 69858), for performance year 2023 and subsequent performance years, we finalized a health equity adjustment to upwardly adjust the MIPS Quality performance score for ACOs that report eCQMs/MIPS CQMs, are high performing on quality, and serve a higher proportion of underserved beneficiaries. As we stated in the CY 2023 PFS final rule, the goals of the health equity adjustment include rewarding ACOs serving a high proportion of underserved beneficiaries and supporting ACOs with the transition to eCQMs/MIPS CQMs (87 FR 69841).

Consistent with the goal of supporting ACOs in their transition to all payer/all patient eCQMs/MIPS CQMs, we are proposing that ACOs that report Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score when calculating shared savings payments. We are proposing to revise § 425.512(b) to specify that, for performance years 2024 and subsequent performance years, we would calculate a health equity adjusted quality performance score for an ACO that reports the three Medicare CQMs or a combination of eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for each measure, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)). This proposal would advance equity within the Shared Savings Program by supporting ACOs that deliver high quality care and serve a high proportion of underserved individuals. Applying the health equity adjustment to an ACO's quality performance category score when reporting Medicare CQMs would encourage ACOs to treat underserved populations.

(5) Summary of Proposals

In Table 25 of this proposed rule we summarize the proposed changes to the regulation at § 425.512(a)(4) and (5) to reflect the proposed changes to the quality reporting requirements and quality performance standard for performance year 2024 and subsequent performance years. Performance benchmarks for performance year 2024 used to determine the 10th, 30th, and 40th percentiles for purposes of evaluating the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(*2*) will be posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library*. We direct readers to the MIPS measure benchmarking policies described at § 414.1380(b)(1)(ii) and to both the quality benchmark and performance period benchmark documentation posted on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library* for more details. Performance benchmarks differ by collection type (that is, eCQM, MIPS CQM, Medicare CQM (as proposed), CMS Web Interface) and are updated for each performance year.

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TABLE 25: Proposed APP Reporting Requirements and Quality Performance Standard for Performance Year 2024 and Subsequent Performance Years

	Performance Year 2024	Performance year 2025 and Subsequent Performance Years*
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface or the 3 eCQMs/MIPS CQMs/Medicare CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.	ACOs are required to report on the 3 eCQMs/MIPS CQMs/Medicare CQMs and administer the CAHPS for MIPS survey. CMS will calculate the two claims-based measures.
Shared Savings Program ACO Quality Performance Standard	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or Reporting the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs and receives a MIPS Quality performance category score under § 414.1380(b)(1), achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, or An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.	Achieving a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring, or An ACO that fails to meet the criterion above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set would share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality performance score. If an ACO (1) does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard or the alternative quality performance standard.

*The CMS Web Interface reporting option sunsets after performance year 2024 and is no longer available beginning with performance year 2025.

c. Proposed APP Measure Set

(1) Background

We refer readers to Table 26, which lists the measures included in the final APP measure set that will be reported by Shared Savings Program ACOs for performance year 2023 and subsequent performance years. These are the same measures finalized in the CY 2023 PFS final rule (87 FR 69862); however, we note that the Collection Type for each measure has been updated. As finalized in the CY 2023 PFS final rule (87 FR 69863), we included the measure type in Table 26 for each measure in the measure set to provide ACOs a list of the outcome measures for purposes of meeting the quality performance incentive for reporting eCQMs/MIPS CQMs. This information is also relevant to the alternative quality performance standard under which ACOs that fail to meet the quality performance standard to qualify for the maximum sharing rate, but that achieve a quality performance score at the 10th percentile on 1 of the 4 outcome measures in the APP measure set, may be eligible to share in savings on a sliding scale (87 FR 69861). We noted inclusion of this information does not change any of the measures in the measure set.

(2) Proposed Revisions

TABLE 26: Measures included in the APP Measure Set for Performance Year 2024 and Subsequent Performance Years [a]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	PRO-PM*
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 236	Controlling High Blood Pressure	eCQM/MIPS CQM/Medicare CQM/CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface**	APM Entity/Third Party Intermediary	Safety	Process
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Process
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface**	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface**	APM Entity/Third Party Intermediary	Chronic Conditions	Process
Quality ID#: 370	Depression Remission at Twelve Months***	CMS Web Interface**	APM Entity/Third Party Intermediary	Behavioral Health	Outcome^

[a] We note that the CMS Web Interface measures: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID#: 438) and Depression Remission at Twelve Months (Quality ID: # 370) do not have benchmarks; and therefore, are not scored for performance year 2024; they are however required to be reported in order to complete the Web Interface data set.

^ Indicates this is an outcome measure.

* Patient-reported outcome-based performance measure (PRO-PM) is a performance measure that is based on patient-reported outcome measure (PROM) data aggregated for an accountable healthcare entity.

**ACOs will have the option to report via the CMS Web Interface for performance year 2024 only.

*** This measure is not included as one of the four outcome measures for purposes of the Quality Reporting Standard as this measure is not scored.

Table 27 includes the proposed eCQM/MIPS CQM measure set for performance year 2024 for the Shared Savings Program and outlines the measure types, which is relevant for ACOs that may elect to report on eCQM/

MIPS CQMs in order to qualify for the incentive under § 425.512(a)(4)(i)(B).

TABLE 27: APP Measure Set for eCQM/MIPS CQM Reporting for Performance Year 2024*

Measure #	Measure Title	Measure Type	SSP Quality Performance Standard	
			MIPS Comparable Measure	Outcome Measure
Quality ID#: 321	CAHPS for MIPS	Patient-Reported Outcome	Yes	No
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Yes	Yes
Measure # 484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Outcome	Yes	Yes
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	Yes	Yes
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	Yes	No
Quality ID#: 236	Controlling High Blood Pressure	Intermediate Outcome	Yes	Yes

* We note that Medicare CQM is not one of the collection types included in the eCQM/MIPS CQM incentive under § 425.512(a)(4)(i)(B).

Table 28 identifies the preliminary measures for the Universal Foundation's adult component.

TABLE 28: Preliminary Adult Universal Foundational Measures [a]^

Domain	Identification Number and Name
Wellness and prevention	139: Colorectal cancer screening 93: Breast cancer screening 26: Adult immunization status
Chronic conditions	167: Controlling high blood pressure 204: Hemoglobin A1c poor control (>9%)
Behavioral health	672: Screening for depression and follow-up plan 394: Initiation and engagement of substance use disorder treatment
Seamless care coordination	561 or 44: Plan all-cause readmissions or all- cause hospital readmissions
Person-centered care	158 (varies by program): Consumer Assessment of Healthcare Providers and Systems overall rating measures
Equity	Identification number undetermined: Screening for social drivers of health

[a] Domains are from Meaningful Measures 2.0. Identification numbers are CMS Measures Inventory Tool measure family identification numbers; names reflect the descriptions associated with those numbers.

^ Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS – The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

* Quality ID #487 Screening for social drivers of health is an available MIPS CQM for PY 2023; the MIPS CQM Specification is available at *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_487_MIPSCQM.pdf.*

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The CMS Web Interface collection type under the APP includes 10 measures. We refer readers to Table Group E of Appendix 1 of this proposed rule for the proposed substantive changes to measure specifications for 9 out of 10 CMS Web Interface measures starting with performance year 2024. As proposed, the changes would update measures and align the CMS Web Interface measures with the practice

workflows of the MIPS CQM collection type.

d. Proposals To Modify the Health Equity Adjustment Underserved Multiplier

(1) Background

Consistent with our goal of rewarding ACOs that include a higher proportion of underserved beneficiaries while delivering high quality care, we finalized in the CY 2023 PFS final rule (87 FR 69836 through 69857) the application of a health equity adjustment that adds up to 10 bonus points to an ACO's MIPS Quality performance category score based on certain criteria. The health equity adjustment is applied to an ACO's MIPS quality performance category score when the ACO reports the three all-payer eCQMs/MIPS CQMs in performance year 2023 and, as proposed in section III.G.2.b.(2) of this proposed rule, the three eCQMs/MIPS CQMs/Medicare CQMs starting in performance year 2024. To qualify for the health equity adjustment, the ACO must also meet the data completeness requirement at § 414.1340 and administer the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)). The health equity adjustment is conditional on (1) high quality measure performance and (2) providing care for a proportion of underserved populations greater than or equal to a predetermined floor.

The goal of the health equity adjustment is to reward ACOs with high performance scores on quality measures and that serve a high proportion of underserved beneficiaries. Correspondingly, the health equity adjustment bonus points are calculated by multiplying the ACO's performance scaler by the ACO's underserved multiplier. An ACO's performance scaler is designed to identify top performance among ACOs reporting all-payer eCQMs/MIPS CQMs in performance year 2023 and, as proposed in section III.G.2.b.(2) of this proposed rule, eCQMs/MIPS CQMs/Medicare CQMs in performance year 2024. The performance scaler is an aggregated value across all eCQM/MIPS CQM measures and is determined based on if the ACO's measure performance was in the top, middle, or bottom third of ACO performance for that performance year. We refer readers to section III.G.4.b.(7).c of the CY 2023 PFS final (87 FR 69843 through 69845) for more details on the performance scaler calculation. The underserved multiplier is designed to identify ACOs serving high proportions of underserved beneficiaries. As described in the CY 2023 PFS final rule (87 FR 69845 through 69849), the underserved multiplier is a proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of: (1) the proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85; or (2) the proportion of the ACO's assigned beneficiaries who are enrolled in Medicare Part D low-income subsidy (LIS) or are dually eligible for Medicare and Medicaid. The use of both the ADI and Medicare and Medicaid dual eligibility or LIS status to assess underserved populations in the health equity adjustment allows CMS to consider both broader neighborhood level characteristics and individual characteristics among CMS beneficiaries.

The CY 2023 PFS final rule did not state how CMS intended to compute the proportion of beneficiaries with an ADI national percentile rank of at least 85 with respect to beneficiaries for whom a numeric national percentile rank value is not available. We do not believe it is appropriate to assign a zero to the beneficiaries without an ADI national percentile rank in the calculation. Doing so would unfairly disadvantage ACOs with such beneficiaries vis-à-vis those ACOs with beneficiaries that all have an ADI national percentile rank by lowering their scores. The CY 2023 PFS final rule (87 FR 69846) stated that the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 is computed using the number of assigned beneficiaries. A footnote stated that in computing the proportion of beneficiaries dually eligible for Medicare and Medicaid, we would use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid. In response to public comment, we finalized the proposal to include LIS as a modification to the calculation of the underserved multiplier (87 FR 69849). In calculating the LIS proportion, CMS uses the same methodology it adopted for calculating dually eligible beneficiaries: person years.

(2) Proposed Revisions

We propose to revise the underserved multiplier calculation to specify the calculations in more detail and bring greater consistency between the calculation of the proportion of ACOs' assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 and the proportion of ACOs' assigned beneficiaries who are enrolled in Medicare Part D LIS or are dually eligible for Medicare and Medicaid. Specifically, we propose to remove beneficiaries who do not have a numeric national percentile rank available for ADI from the health equity adjustment calculation for performance year 2023 and subsequent performance years. Beneficiaries without a national percentile ADI rank would appear neither in the numerator nor in the denominator of the proportion.

While we established a policy for the treatment of aligned beneficiaries for whom an ADI national percentile rank could not reasonably be calculated for use in the advance investment payments risk factors-based score (87 FR 69796 through 69797), we neither proposed nor finalized a policy for such beneficiaries with respect to the calculation of the health equity adjustment underserved multiplier—nor do we believe the policy we finalized for AIP is appropriate for calculating the health equity adjustment. In the CY 2023 PFS final rule (87 FR 69800), we finalized the use of imputing a value of 50 for the ADI national percentile rank if there is insufficient data to match a beneficiary to an ADI national percentile rank for calculating AIP risk factors-based scores. There are important differences in the implications of using an imputed value of 50 for calculating the AIP risk factors-based scores and for calculating the underserved multiplier. The imputed ADI ranking of 50 corresponds to the average national ADI ranking and would be the most neutral imputed value and would avoid biasing an ACO's payments in either direction for risk factor-based scores in the AIP calculation. The use of an ADI ranking of 50 in the underserved multiplier, however, would result in that beneficiary not counting in the numerator of the underserved multiplier proportion because only beneficiaries with an ADI of at least 85 are counted in the numerator. Therefore, we are proposing to exclude beneficiaries without a national percentile ADI rank from the health equity adjustment underserved multiplier. This approach is more equitable because it will remove a beneficiary without an ADI rank from the denominator and the numerator of the calculation of an ACO's underserved multiplier instead of penalizing ACOs that have such beneficiaries.

It is in the public interest to apply this change starting with performance period

2023. Section 1871(e)(1)(A)(ii) of the Act authorizes the Secretary to retroactively apply a substantive change in Medicare regulations if the Secretary determines that failure to apply the change retroactively would be contrary to the public interest. Here, applying this change starting with performance period 2023 is in the public interest because, absent further specification of how to treat beneficiaries without a national percentile ADI rank current policy may unfairly penalize ACOs for reasons beyond their control. Current policy counts beneficiaries with missing ADI ranks in the underserved multiplier denominator and contributes zero to the numerator, thereby reducing the health equity adjustment for ACOs with such beneficiaries and harming their ability to meet the quality performance standard and receive shared savings.

Separately, we propose to modify the calculation of the proportion of assigned beneficiaries dually eligible for Medicare and Medicaid and the calculation of the proportion of assigned beneficiaries enrolled in LIS to use the number of beneficiaries rather than person years for calculating the proportion of the ACO's assigned beneficiaries who are enrolled in LIS or who are dually eligible for Medicare and Medicaid starting in performance year 2024. For example, when calculating the underserved multiplier component of the health equity adjustment to an ACO's quality performance score for ACOs that report the three eCQMs/MIPS CQMs/Medicare CQMs, the proportion would be equal to the number of assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by total number of assigned beneficiaries. We are not proposing to alter the calculation of the proportion of beneficiaries residing in a census block group with an ADI national percentile rank of at least 85, which is already based on the number of assigned beneficiaries. Person years would continue to be used in financial calculations where beneficiary experience is stratified into by Medicare enrollment type (ESRD, disabled, aged/dual eligible, and aged non/dual eligible) and it is important to account for partial year enrollment to ensure accuracy. The proposed policy change would bring greater consistency between the two proportions used in determining the underserved multiplier. It also acknowledges that beneficiaries with partial year as compared to full year LIS enrollment or dual eligibility are also socioeconomically vulnerable and strengthens incentives for ACOs to serve this population. Further, inclusion of beneficiaries with partial year LIS enrollment in the underserved multiplier provides increased incentive for ACOs to help facilitate LIS enrollment for beneficiaries who meet eligibility criteria.

We seek comment on these proposals.

e. Proposal To Use Historical Data To Establish the 40th Percentile MIPS Quality Performance Category Score

(1) Background

In the CY 2023 PFS final rule (87 FR 69858), we finalized that beginning performance year 2024, one of the ways for an ACO to meet the Shared Savings Program quality performance standard and share in savings at the maximum rate under its track (or payment model within a track) is for the ACO to achieve a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility based-scoring.

In the CY 2022 PFS proposed and final rules (86 FR 39274 and 86 FR 65271), we stated that, for a given performance year, the 30th or 40th percentile across all MIPS Quality performance category scores would be calculated after MIPS final scoring is complete based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. Therefore, we are not able to provide performance rate information prior to or during the performance year. Nevertheless, we stated that we believe that publicly displaying prior year performance scores that equate to the 30th and 40th percentile across all MIPS Quality performance category scores for the applicable performance year would still provide helpful information for ACOs to determine what level of quality performance they would need to meet in order to satisfy the quality performance standard under the Shared Savings Program. We stated that we would release this historical information on the Shared Savings Program website when it becomes available.

In the CY 2022 PFS proposed rule (86 FR 39274), we also explained that interested parties have expressed concerns regarding the lack of information on the level of quality performance that would equate to the 30th or 40th percentile MIPS Quality performance category score and that would enable an ACO to be eligible to share in savings or to avoid maximum shared losses, if applicable. We noted that interested parties have expressed concern that these data are not publicly available prior to the start of a performance year and that they do not believe that ACOs have a way of determining what quality score they would need to achieve to meet the quality performance standard.

In the CY 2022 PFS proposed rule (86 FR 39274), we also solicited comment on whether publicly displaying prior year performance scores that equate to the 30th or 40th MIPS Quality performance category scores would help to address ACOs' concerns regarding the lack of advance information regarding the quality performance score they must meet in order to satisfy the quality performance standard under the Shared Savings Program. Several commenters supported publicly displaying prior year performance scores that equate to the 30th or 40th percentile across all MIPS Quality category performance scores, and one commenter expressed concern that publicly displaying prior year performance scores is not the optimal way to address concerns of interested parties and indicated that performance is volatile and the 30th (or 40th) percentile may change significantly from year to year depending upon changes in quality performance in MIPS (86 FR 65271).

We clarified in the CY 2023 PFS proposed rule (87 FR 46148) and final rule (87 FR 69867) that we use the submission-level MIPS Quality performance category scores (unweighted distribution of scores) to determine the 30th percentile and 40th percentile MIPS Quality performance category scores for purposes of establishing the applicable quality performance standard under the Shared Savings Program. In light of public comments and concerns about the predictability of the 40th percentile MIPS Quality performance category score due to changes in MIPS scoring policies over time—including MIPS scoring changes impacting measures that lack a benchmark or case minimum as described at § 414.1380(b)(1)(i)(A), measure achievement points as described at paragraph (b)(1)(i), new measures (years 1 and 2 of a measure's use) as described at paragraph (b)(1)(i)(C), new sub-group reporting option as described at § 414.1318(a), and MIPS High Priority and End to End Bonus Points as described at § 414.1380(b)(1)(v)—and as a result of the concerns expressed by ACOs and other interested parties and as we gain experience with aligning Shared Savings Program reporting and scoring policies with MIPS, we believe that a revised methodology is needed to calculate the 40th percentile MIPS Quality performance category score for

the quality performance standard for performance year 2024 and subsequent performance years.

As MIPS scoring policies evolve over time, changes in MIPS scoring policy have the potential to adjust the year-to-year comparability of MIPS Quality performance category scores. Between performance years 2022 and 2023, there were MIPS policy changes to measures that lack a benchmark or case minimum as described at § 414.1380(b)(1)(i)(A), measure achievement points as described at paragraph (b)(1)(i), new measures (years 1 and 2 of a measure's use) as described at paragraph (b)(1)(i)(C), and a new sub-group reporting option as described at § 414.1318(a). Additionally, MIPS High Priority and End to End Bonus Points were sunset in performance year 2022 as described at § 414.1380(b)(1)(v). The projected 40th percentile MIPS Quality performance category score for performance year 2023 does not reflect these proposed methodological changes. To minimize reliance on a single year of performance data, the use of multiple years of historical data could be used to ''smooth'' out the impact of MIPS scoring policy changes on the quality performance standard in any one year. At the same time, using too many years of data to average scores might include a greater number of years that don't reflect current policies.

(2) Proposed Revisions

For performance year 2024 and subsequent performance years, we propose to use historical submission-level MIPS Quality performance category scores to calculate the 40th percentile MIPS Quality performance category score. Specifically, we propose to use a rolling 3-performance year average with a lag of 1 performance year (for example, the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 would be based on averaging the 40th percentile MIPS Quality performance category scores from performance years 2020 through 2022). We believe that our proposal to use a 3-year historical average is consistent with the proposal under section IV.A.4.h.(2) of this proposed rule that would permit, for purposes of establishing a performance threshold as identified in § 414.1405(b), a time span of up to three consecutive performance periods for performance year 2024 and subsequent performance years.

We would provide ACOs with the performance score that equates to the 40th percentile MIPS Quality performance category score that would be used as the quality performance standard for a given performance year prior to the start of the performance year (for example, the 40th percentile MIPS Quality performance category score based on historical data and applicable for performance year 2024 would be released on the Shared Savings Program website in December 2023).

The use of 3 historical base years would mitigate issues that may arise from using a single year historical reference such as scoring, policy, and/or performance anomalies, such as a pandemic, specific to the historical base year. Additionally, the use of historical data would allow additional time for data availability and limit the potential impact of MIPS Targeted Review as described at § 414.1385 and other MIPS scoring corrections. This approach is also responsive to the concerns ACOs, and other interested parties have with the predictability of the current method of calculating the 40th percentile MIPS Quality performance category score. However, we acknowledge that by using historical benchmarks, the benchmark would not reflect the most recent policies, measure specifications, and scores. For example, the historical base years are 2–4 years removed from the performance year and could reflect data that may have anomalies specific to the base year that would render those data inconsistent with the performance year's quality performance. Additionally, changes to measure specifications for measures included in the APP measure set may result in the historical base period including measures that are different than the corresponding measures that were applicable during the performance year. This could further reduce the comparability of historic base year data with the performance year's quality performance data.

Table 29 shows the 40th percentile MIPS Quality performance category scores for performance years 2018 through 2021 based on the current methodology as published in the CY 2023 PFS final rule (87 FR 69868). The proposed methodology would be effective for performance year 2024 and subsequent performance years. We have added to Table 29 the projected 40th percentile MIPS Quality performance category scores for performance years 2022 and 2023 based on the proposed methodology for illustrative purposes. The projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2022 is based on the average of the 40th percentile MIPS Quality performance category scores from performance years 2018 through 2020, and the projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2023 is based on the average of the 40th percentile MIPS Quality performance category scores from performance years 2019 through 2021. The years are averaged at equal weights. For example, we would calculate the projected 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2022 by first summing the 2018 (70.80), 2019 (70.82), and 2020 (75.59) 40th percentile Quality performance category score values to arrive at a value of 217.21 [70.80 + 70.82 + 75.59 = 217.21]. We would then divide the value of 217.21 by three (the number of years included in the historical reference period) to arrive at a projected 40th percentile MIPS Quality performance category score of 72.40 for 2022 [217.21 ÷ 3 = 72.40]. Note that this example illustrates averaging the 2018, 2019, and 2020 40th percentile MIPS Quality performance category score values.

TABLE 29: 40th Percentile MIPS Quality Performance Category Scores Using Current and Proposed Methodology

Performance Year	40th percentile MIPS Quality performance category score*
2018	70.80*
2019	70.82*
2020	75.59*
2021	77.83*
2022 (projected)	72.40^
2023 (projected)	74.75^

* As published in Table 64 of the CY 2023 PFS final rule (87 FR 69868). The 40th percentile MIPS Quality performance category score was calculated by taking the 40th percentile of all submission-level MIPS Quality performance category scores (the unweighted distribution of scores), excluding entities/providers eligible for facility-based scoring.

^ As projected based on the proposed methodology. The performance year 2022 projected 40th percentile MIPS Quality performance category score for the quality performance standard is based on the average of the 2018, 2019, and 2020 40th percentile MIPS Quality performance category scores. The performance year 2023 projected 40th percentile MIPS Quality performance category score for the quality performance standard is based on the average of the 2019, 2020, and 2021 40th percentile MIPS Quality performance category scores.

We seek comment on our proposal to use a 3-performance year rolling average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 and subsequent performance years. Using a 1-year lag would help ensure the availability of base period data by limiting the possibility that data availability is negatively impacted by scoring, policy, and/or performance anomalies from the prior performance year. In the development of our proposal to use a 3-performance year rolling average with a lag of 1-performance year to calculate the 40th percentile MIPS Quality performance category score used for the quality performance standard for performance year 2024 and subsequent performance years, we considered another alternative methodology, which was to establish a historical quality performance standard based on the year immediately prior to the performance year's quality performance score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We also seek comment on other alternative methodologies we should consider to calculate the 40th percentile MIPS Quality performance category score for the quality performance standard.

f. Proposal To Apply a Shared Savings Program Scoring Policy for Excluded APP Measures

(1) Background

In the CY 2021 PFS final rule (85 FR 84720 through 84734), we finalized an approach that aligns the Shared Savings Program quality performance scoring methodology with the MIPS scoring methodology. We also stated that for each quality measure that an ACO submits that has significant changes, the total available measure achievement points are reduced by 10 points under the APP under current MIPS scoring policy (§ 414.1380(b)(1)(vii)(A)) (85 FR 84725)). In the CY 2021 PFS final rule (85 FR 84901), we finalized policies at § 414.1380(b)(1)(vii)(A) to provide that for each measure under MIPS that is submitted, if applicable, and impacted by significant changes, performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. We stated that ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. As described at § 414.1380(b)(1)(vii)(A), measures that are excluded due to significant changes are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points.

In performance year 2022, two of the eCQMs/MIPS CQMs that are part of the APP measure set were excluded from MIPS measure achievement points and total available measure achievement points for the MIPS Quality performance category under § 414.1380(b)(1)(vii)(A). Specifically, the eCQM version of the Preventive Care and Screening: Screening for Depression and Follow-up Plan measure (Quality ID #134) and the Controlling High Blood Pressure measure (Quality ID #236) were excluded. Thus, under MIPS scoring policies, ACOs reporting one or both of these measures had their total measure achievement points and total available measure achievement points reduced by 10 (for reporting one measure) or 20 (for reporting both measures) points, respectively. Under the APP, these ACOs were still required to report all 6 measures; however, their performance year 2022 MIPS Quality performance category score was based on the 4 or 5 non-excluded measures (depending on whether the ACO reported one or both excluded measures) in the APP measure set. Consequently, the resulting MIPS Quality performance category score for an ACO that would have performed well on the excluded quality measures would be lower than it otherwise would have been if those measures were not excluded. Alternatively, if an ACO would have performed poorly on the excluded quality measures, then the resulting MIPS Quality performance category score would be higher than it otherwise would have been if those measures were not excluded. In either scenario, an ACO is required to report quality performance for all measures under the APP and has no control over

whether and which measures are excluded.

(2) Proposed Revisions

Given that the Shared Savings Program does not determine which quality measures are excluded and that ACOs do not have a choice of measures they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the ACOs' control, such as in the event a measure is excluded. Therefore, we are proposing that, for performance year 2024 and subsequent performance years, if (1) an ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1), and (2) the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced due to measure exclusion under § 414.1380(b)(1)(vii)(A), then we would use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, to determine whether the ACO meets the quality performance standard required to share in savings at the maximum rate under its track (or payment model within a track), for the relevant performance year. This policy aims to alleviate the potential adverse impacts to shared savings determinations that may arise in the event that one or more of the quality measures required under the APP is excluded. We are also proposing to make conforming changes to the regulation text § 425.512 by revising paragraph (a)(5)(i) and adding paragraph (a)(7).

We finalized in the CY 2023 PFS final rule (87 FR 69845) that unscored measures are removed from the calculation of an ACO's health equity adjustment, effectively receiving a performance scaler of 0 for those measures. However, we inadvertently did not codify this policy in the Code of Federal Regulations. Therefore, in this proposed rule, we are proposing to codify this policy by revising § 425.512(b)(3)(ii)(B) to state that CMS assigns a value of 0 for each measure that CMS does not evaluate because the measure is unscored. We propose that the regulation text changes would be effective for performance year 2023 and subsequent performance years as the policy was finalized in the CY 2023 PFS final rule to calculate the health equity adjustment for performance year 2023 and subsequent performance years.

We are also proposing that quality measures impacted by the MIPS policy at § 414.1380(b)(1)(vii)(A) are unscored measures for the purposes of calculating the health equity adjustment; therefore, excluded measures would not render an ACO ineligible for the health equity adjustment as long as the ACO reports all required measures under the APP and meets the data completeness requirement at § 414.1340 for all required measures and receives a MIPS Quality performance category score under § 414.1380(b)(1).

As discussed in section IV.A.4.g.(1)(c)(i) of this proposed rule, we are proposing a change to the MIPS policy to remove the 10 percent threshold for changes to codes, clinical guidelines, or measure specifications for all measure types. We believe that our proposal to apply a floor to an ACO's Quality performance category score in determining the ACO's quality performance standard in the event that the ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score for the performance year is reduced under § 414.1380(b)(1)(vii)(A) functions in concert with our proposal under section IV.A.4.g.(1)(c)(i) of this proposed rule. We refer readers to section IV.A.4.g.(1)(c)(i) of this proposed rule for further discussion of our proposal to change the MIPS scoring policy.

g. Proposal To Require Spanish Language Administration of the CAHPS for MIPS Survey

(1) Background

CMS has created official translations of the CAHPS for MIPS survey in 7 languages, including Spanish, Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese (81 FR 77386), in addition to the required administration of English survey. However, use of these translations is mostly voluntary, with the exception of a requirement to administer the Spanish translation of the CAHPS for MIPS Survey for patients residing in Puerto Rico. Organizations (groups, virtual groups, subgroups, and APM entities) that elect CAHPS for MIPS must contract with a CMS-approved survey vendor to administer the survey and must request survey translations for the vendor to administer the survey in an optional language. Generally, the use of survey translations adds additional survey administration cost to the organization.

(2) Proposed Revisions

As discussed in section IV.A.4.f.(1)(c)(ii) of this proposed rule, we are proposing to require Spanish language administration of the CAHPS for MIPS survey for MIPS eligible clinicians reporting MIPS. Specifically, we are proposing to require MIPS eligible clinicians to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines beginning with 2024 survey administration. This should better ensure that we are assessing the experience of patients who are Spanish-speaking and with limited English proficiency, and is part of our efforts to advance health equity. We refer readers to section IV.A.4.f.(1)(c)(ii) of this proposed rule for further discussion of our proposal related to the CAHPS for MIPS survey. In addition, we are interested in gathering information directly from organizations that administer the CAHPS for MIPS Survey on whether they consider to request the vendor to administer the survey in one or more of the available survey translations based on the language preferences of patients. We are also interested in learning about the factors that more or less likely affect the administration of survey translations where there is need for one or more of the available translations.

h. Proposals To Align CEHRT Requirements for Shared Savings Program ACOs With MIPS

(1) Background

Many of our programs require the use of certified electronic health record (EHR) technology (CEHRT), including the Quality Payment Program, Shared Savings Program, and other value-based payment initiatives. With respect to the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies. In addition, section 1899(b)(3)(D) of the Act authorizes the Secretary to incorporate reporting requirements and incentive payments from section 1848 of the Act into the Shared Savings Program, such as requirements and payments related to electronic prescribing and electronic health

records, including using alternative criteria for determining whether to make such incentive payments. Pursuant to these authorities, we have incorporated reporting requirements related to the adoption and use of CEHRT in our regulations, including specifically cross-referencing the Quality Payment Program's definition of CEHRT (42 CFR 414.1305) in our regulatory definition of CEHRT at § 425.20. For the Shared Savings Program and Quality Payment Program, CEHRT currently is defined at § 414.1305 as EHR technology (which could include multiple technologies) certified by the Office of the National Coordinator for Health Information Technology (ONC) under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, set forth at 45 CFR 170.102, and a designated set of the 2015 Edition health information technology (IT) certification criteria as further provided therein.

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), sections 13001 through 13424 of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, February 17, 2009), established ONC under the Department of Health and Human Services, authorizing ONC to adopt standards for certifying health IT. ONC has codified its standards, implementation specifications, certification criteria, and certification program for health IT under 45 CFR part 170. Specifically, ONC has codified its certification criteria for health IT, including EHRs, at 45 CFR 170.315. Currently referred to as the ''2015 Edition health IT certification criteria.'' For more information regarding ONC's current policies, standards, and certification requirements for health IT, please refer to 45 CFR part 170, particularly § 170.315, and the ONC Certification of Health IT website at: *https://www.healthit.gov/topic/certification-ehrs/certification-health-it*.

In the CY 2019 PFS final rule (83 FR 59982 through 59988), we adopted three key requirements related to ACOs use of CEHRT, beginning with the performance years starting on January 1, 2019.

First, ACOs must certify annually, at the end of each performance year, that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage during the current performance year. The ACO's eligible clinicians must use CEHRT that meets the definition in our regulation at § 425.20, which provides that CEHRT has the same meaning as under the Quality Payment Program at § 414.1305. Specifically, we updated our regulations at § 425.506(f) to reflect that, beginning with the performance years starting on January 1, 2019:

- ACOs in a track that does not meet the financial risk standard to be an Advanced APM, which includes ACOs participating under BASIC track Levels A through D, must certify annually that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers.
- ACOs in a track that meets the financial risk standard to be an Advanced APM, which includes ACOs participating under BASIC track Level E or the ENCHANCED track, must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under the Quality Payment Program at § 414.1415(a)(1)(i). Under this requirement, for Performance Periods beginning in 2019, 75 percent of eligible clinicians must use CEHRT to document and communicate clinical care to their patients or health care providers.

Second, we also revised the Shared Savings Program requirements for data submission and certifications at § 425.302(a)(3)(iii) to require the ACO to certify at the end of each performance year, that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

Finally, we updated our regulations at § 425.20 to incorporate the definition of CEHRT at § 414.1305 that applies under the Quality Payment Program. The Quality Payment Program's regulation at § 414.1305 defines CEHRT as EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition at 45 CFR 170.102 and has been certified as meeting certain other criteria set forth in ONC's 2015 Edition health IT certification criteria at 45 CFR 170.315 as further described in § 414.1305. Applying the Shared Savings Program's definition at § 425.20, ACOs under the Shared Savings Program must use EHR technology meeting the Quality Payment Program's definition of CEHRT at § 414.1305to meet the requirements set forth in our regulation at § 425.506(f). As discussed in section III.R. of this proposed rule, in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule (88 FR 23758), which appeared in the April 18, 2023 **Federal Register**, ONC has proposed to discontinue the year-themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC is proposing to instead maintain a single set of ''ONC Certification Criteria for Health IT,'' which would be updated in an incremental fashion in closer alignment to standards development cycles and regular health information technology (IT) development timelines (88 FR 23750). As further discussed in section III.R. of this proposed rule, we are proposing to modify the Quality Payment Program's definition of CEHRT at § 414.1305 to flexibly incorporate any changes by ONC to its definition of Base EHR and its certification criteria for Health IT.

(2) Removing CEHRT Use Threshold Requirements and Requiring Reporting of the MIPS Promoting Interoperability Performance Category

In order to streamline CEHRT threshold requirements for ACOs and align with the Quality Reporting Program's Merit-Based Incentive Payment System (MIPS), we propose to sunset the Shared Savings Program CEHRT threshold requirements and modify our regulations at § 425.506(f) to indicate that they will be applicable only through performance year 2023. We further propose, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this subchapter) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We propose to codify this new requirement at § 425.507.

Specifically, we propose that any requirements applicable to MIPS eligible clinicians reporting on objectives and measures specified by CMS for the MIPS PI category would apply to MIPS eligible clinicians, QPs, and Partial QPs participating in an ACO at § 425.507(a). We further propose that if any of these requirements for a MIPS eligible clinician reporting for the MIPS PI category, including objectives and measures, are amended through rulemaking (such as adoption, modification, or removal of an objective or measure), then the new or modified requirements will also be applicable to MIPS eligible clinicians, QPs, and Partial QPs participating in an ACO under § 425.507. For instance, in section IV.A.4.f.(4) of this proposed rule, we are proposing several modifications to the MIPS PI performance category's requirements, including modifying the performance period at § 414.1320 as well as specific measures such as the High Priority Safety Assurance Factors for EHR Resilience (SAFER) Guides measure. To the extent these or other policies are finalized through rulemaking, then these requirements would also be applicable to ACO participants as provided by our proposal here.

To further align with applicable requirements for the MIPS Promoting Interoperability performance category, we are proposing that MIPS eligible clinicians, QPs, Partial QPs, and ACOs as APM entities may be exempt from our proposed regulation at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity: (1) does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii); (2) is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or (3) has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS PI performance category as an individual, group, or virtual group or the ACO reports MIPS PI performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QP the exemption would not apply for purposes of satisfying our proposed regulation at § 425.507.

Exclusions to MIPS eligible clinicians described at § 414.1310(b)(1)(iii) include eligible clinicians who do not exceed the MIPS low volume threshold. Eligible clinicians who are not MIPS eligible clinicians have the option to voluntarily report measures and activities for MIPS as described at § 414.1310(b)(2). Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHC) who provide services that are billed exclusively under the FQHC or RHC payment methodologies may voluntarily report the MIPS PI performance category as a group, virtual group, or APM entity. MIPS eligible clinicians, QPs, and Partial QPs practicing in FQHCs or RHCs who provide services that are billed exclusively under FQHC or RHC payment methodologies may voluntarily report the MIPS PI performance category as an individual, group, virtual group, or APM entity. It is important to note that exclusions to MIPS eligible clinicians as described at § 414.1310(b)(1)(i) and (ii) are not applicable to our proposal at § 425.507 because QPs and Partial QPs are required to report MIPS PI performance category for purposes of satisfying the Shared Savings Program proposal at § 425.507. Examples of applicable exclusions under § 414.1380(c)(2) for reweighting of the MIPS PI performance category include, but are not limited to, the following:

- MIPS eligible clinicians, QPs, and Partial QPs participating in the ACO who are granted a hardship exception under § 414.1380(c)(2)(i)(C) at the individual, group, virtual group, or APM entity level.
- MIPS eligible clinicians, QPs, and Partial QPs that are eligible for reweighting of the PI performance category at the individual, group, virtual group, or APM entity level as described at § 414.1380(c)(2)(i)(A)(4).
- MIPS eligible clinicians, QPs, and Partial QPs that are eligible for reweighting of the PI performance category as described at § 414.1380(c)(2)(i)(A)(*4*).

We believe that incorporating MIPS PI performance category's requirements into the Shared Savings Program will alleviate the burden that the current policy creates for ACOs. Because the Shared Savings Program CEHRT attestation requirement and the MIPS PI category requirements are not the same, ACOs have the burden of managing compliance with two different CEHRT program requirements. In finalizing the Shared Savings Program CEHRT attestation in the CY 2019 PFS, we stated our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center (83 FR 59983). Given our unified goal and vision for the use of CEHRT, we believe our proposal at § 425.507 will allow ACOs to focus on a unified set of program requirements for the use of CEHRT and reduce the administrative burden of managing compliance with a different set of program requirements with the same aim.

While ACOs would be able to report the MIPS PI category at the individual, group, virtual group, or APM entity level for purposes of satisfy our proposal at § 425.507, we encourage ACOs to evaluate reporting the MIPS PI performance category at the APM entity level for purposes of satisfying the Shared Savings Program regulation proposed at § 425.507. In the CY 2023 PFS final rule, we finalized a policy to introduce a voluntary reporting option for APM entities to report the MIPS PI performance category at the APM entity level beginning with the CY 2023 performance period (87 FR 70033). For purposes of MIPS scoring and payment adjustments, if the ACO reports the MIPS PI performance category at the APM entity level, the APM entity PI performance category score would be used to generate the APM entity level score for purposes of scoring the MIPS PI performance category. If the ACO does not report PI at APM entity level, the ACO's individual and group scores would be calculated as a weighted average up to the APM entity level to generate the APM entity level score for purposes of scoring the MIPS PI performance category. If an eligible clinician reports PI at the individual or group level under traditional MIPS or

the APM Performance Pathway (APP) in addition to reporting the MIPS PI performance at the APM entity level via the APP, for purposes of MIPS scoring and payment adjustments, that eligible clinician would receive the higher of their individual, group, or APM entity PI performance category score. For more information about reporting the PI performance category at the APM entity level, we direct readers to the MIPS Promoting Interoperability User Guide, which is updated each performance year, in the QPP Resource library *https://qpp.cms.gov/resources/resource-library*. We anticipate releasing sub-regulatory guidance for ACOs that participate in the Shared Savings Program about voluntarily reporting the MIPS PI performance category at the APM entity level in future performance years.

We are seeking public comment on our proposal that, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We propose to codify this new requirement at § 425.507.

We are also seeking public comment on an alternative proposal to narrow the proposal to require that ACOs to report the measures and requirements under the MIPS PI performance category, in accordance with our regulations at 42 CFR part 414 subpart O, at the APM entity level. This alternative proposal would remove the option for MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO to report the MIPS PI performance category at the individual, group, or virtual group level for purposes of satisfying our proposal at § 425.507.

(3) Updating Public Reporting Requirements

As described in the CY 2019 final rule (80 FR 32813 through 32815), we believe that one important aspect of patient-centered care is patient engagement and transparency, which can be achieved by the public reporting of ACO quality and cost performance. Public reporting helps to hold ACOs accountable and may improve a beneficiary's ability to make informed health care choices as well as facilitate an ACO's ability to improve the quality and efficiency of its care. To ensure our public reporting requirements reflect our proposal to require reporting of objectives, measures, and activities under the MIPS PI performance category as discussed above, we also are proposing to require ACOs to publicly report the number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level as proposed at § 425.507. We are proposing to codify this requirement at § 425.308(b)(9).

We are proposing that MIPS eligible clinicians, QPs, and Partial QPs who would be excluded from reporting under the proposed regulation at § 425.507(b) as discussed previously may be excluded from the number of MIPS eligible clinicians, QPs, or Partial QPs that the ACO publicly reports under our proposed regulation at § 425.308(b)(9). However, if such MIPS eligible clinicians, QPs, and Partial QPs do report the MIPS PI performance category as an individual, group, or virtual group or the ACO reports the MIPS PI performance category as an APM entity, the MIPS eligible clinicians, QPs, and Partial QPs should be included in the number of MIPS eligible clinicians, QPs, and Partial QPs that the ACO publicly reports under our proposed regulation at § 425.308(b)(9).

(4) Updating Annual Certification Requirements

As noted in section III.G.2.h.(2) of this proposed rule, we believe that incorporating MIPS PI performance category's requirements will alleviate confusion for ACOs and the use of CEHRT under the Shared Savings Program. Additionally, we find that the MIPS PI performance category's reporting requirements are more comprehensive and better address the key functions that facilitate better care coordination and quality measurement for ACOs. This change would further align the Shared Savings Program with the MIPS program and allow for greater insight into CEHRT use among ACO clinicians.

Currently, under § 425.302(a)(3)(iii), at the end of each performance year, ACOs must certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable CEHRT threshold percentage specified at § 425.506(f). As discussed in section III.G.2.h.(4). of this proposed rule, we are proposing to sunset the Shared Savings Program CEHRT threshold requirements and modify § 425.506(f) to indicate that they will end with performance year 2023.

To ensure our certification requirements align with our proposal in section III.G.2.h.(2) of this proposed rule, we also propose to revise our regulation at § 425.302(a)(3)(iii) to make the current Shared Savings Program Annual Certification requirement applicable for only performance years 2019 through 2023. That is, we are proposing to sunset the CEHRT certification requirement in the Shared Savings Program by amending regulations to no longer require ACO clinicians to report the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified at § 425.506(f).

We are seeking public comment on our proposal to sunset the CEHRT certification requirement in the Shared Savings Program at §§ 425.302(a)(3)(iii) and 425.506(f) and to add new

requirements at § 425.507, for performance years beginning on or after January 1, 2024, unless otherwise excluded, to require that all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO, regardless of track, satisfy all of the following:

- Report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

++ All MIPS eligible clinicians, QPs, and partial QPs participating in the ACO as an individual, group, or virtual group; or

++ The ACO as an APM entity.

- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements proposed at § 425.507(a) if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

- Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii);
- Is an eligible clinician as defined at § 414.1305 who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2); or
- Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2).

We also seek comment on our proposal to add a new requirement for public reporting in § 425.308(b)(9), requiring that the ACO must publicly report the number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level as proposed at § 425.507.

i. MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs—Request for Information (RFI)

In the CY 2021 PFS proposed rule (85 FR 50232 and 50233), we proposed that for performance year 2021 and subsequent performance years, ACOs would be assessed on a measure set under the APP for Shared Savings Program ACOs. As part of finalizing the APP measure set (85 FR 34727), we stated that the transition to the APP measure set was intended to reduce reporting burden and eliminate differences in the way ACOs are scored compared to their MIPS eligible clinicians, while also moving toward a more outcome-based, primary care focused measure set. Additionally, we stated that we selected the measures to be included because they are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program.

We received public comments raising concerns about the challenges and applicability of these measures to specialists that are part of their ACOs (85 FR 34727). Commenters provided feedback that: reducing the number of ACO quality measures would make specialists less likely to participate in the Shared Savings Program; the proposed measures are not relevant to ophthalmology specialty practices and suggested that the same measure sets used in MIPS be permitted for reporting through the APP or a protocol be put in place to determine if the measures are relevant to the clinicians reporting under the APP; CMS should work with interested parties to refine the current set of measures to make it more appropriate for ACOs, which are responsible for total cost of care for the populations they serve; CMS should clarify if the outcome measures selected are representative of all of the different types of populations that ACOs treat and recommended that CMS take patient compliance and case mix into consideration when selecting measures because some patients may take longer to achieve health goals and ACOs may not have the same relative volume of patients with diagnoses such as diabetes and hypertension.

In the CY 2022 PFS proposed rule (86 FR 39270), we solicited comments on reporting options for specialist providers within an ACO. Specifically, we stated that we have heard from interested parties that the population health/primary care focused measures in the APP are not applicable for specialist providers within an ACO. We noted in the final rule that we may consider feedback we received to inform future rulemaking (86 FR 65264).

In the CY 2022 PFS final rule (86 FR 65376), MVPs were finalized to be available for reporting beginning with the CY 2023 performance period of MIPS, with the notion that MVPs will be implemented through notice and comment rulemaking over the next few years to offer clinically relevant quality reporting for specialists and more granular specialty data (through subgroup reporting) for patients to make informed decisions about the care they receive. In the CY 2022 PFS final rule (86 FR 65376), MVPs were finalized to be available for reporting beginning with the CY 2023 performance period of MIPS, with the notion that MVPs will be implemented through notice and comment rulemaking over the next few years to offer clinically relevant quality reporting for specialists and more granular specialty data (through subgroup reporting) for patients to make informed decisions about the care they receive. Building upon our commitment to align quality measures across CMS,[150] we direct readers to section IV.A.4.a. of this proposed rule where we propose to create a primary care MVP. We note that the primary care MVP would create continuity between the primary care measures assessed under MIPS and the measures providers would be accountable for in the Medicare Shared Savings Program.

In light of the public comments described above and the finalization and continued development of the MVPs, we believe we need incentives for specialists in Shared Savings Program ACOs to report clinically relevant quality measures and to allow patients, referring clinicians, and ACOs to have more information regarding specialists involved in patient care. We believe that encouraging specialists to report on MVPs will lead to increased specialty engagement in the Shared Savings Program, thereby holding specialists accountable for quality improvement.

Beginning in CY 2023, specialists that report under MIPS, including specialists that participate in Shared Savings Program ACOs, have the option to register to report MVPs for the applicable CY performance period as described at § 414.1365(b) as a group, subgroup, or individual and to report on relevant MVP quality measures as described at § 414.1365(c). In this proposed rule, we are soliciting comments on scoring incentives that would be applied to an ACO's health equity adjusted quality performance score beginning in performance year 2025 when specialists who participate

[150] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

in the ACO report quality MVPs as described at § 414.1365(c)(1).

Similar to the health equity adjustment finalized in the CY 2023 PFS final rule (87 FR 69838), we are considering bonus points for ACOs with specialists reporting quality MVPs as described at § 414.1365(c)(1) that would be applied after MIPS scoring is complete. ACOs may receive up to a maximum of 10 additional points added to their ACO's health equity adjusted quality performance score if they meet the data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1), in addition to administering the CAHPS for MIPS survey. In addition to specialists that participate in the ACO reporting quality MVPs described at § 414.1365(c)(1), an ACO would be required to report all measures in the APP measure set, meet the data completeness requirement at § 414.1340 and receives a MIPS Quality performance category score under § 414.1380(b)(1) to be eligible for bonus points.

Our overarching intent is to have specialists participate in ACOs in a meaningful way and to collect quality data that is comparable to data reported by other specialty providers in quality MVPs. We are seeking feedback on our overall approach to align quality measures in the Adult Universal Foundation with measures used for evaluation in the Medicare Shared Savings Program. We are also seeking feedback on the following aspects of MVP reporting for specialists in Shared Savings Program ACOs:

- In order to highlight specialty clinical practice within ACOs, how should we encourage specialist reporting of MVPs?
- How should we encourage the reporting of MVPs to collect quality data that is comparable to data reported by other specialty providers in quality MVPs and to address clinician concerns over measure appropriateness?
- How should we consider encouraging specialists to report the MVP that is most relevant to their clinical practice?
- How should we distinguish bonus points for ACOs that report on a larger volume of patients through MVPs?
- How should we provide ACOs with bonus points to their health equity adjusted quality performance score when an ACO's specialty clinicians report MVPs?
- What concerns and considerations should we be aware of when assessing ACOs for quality performance based on reporting quality measures within MVPs?
- Would incentivizing specialty MVPs create a disincentive for ACOs to report primary care focused APP and/or MVP measures?
- In the event that MIPS quality measures in MVPs are excluded under § 414.1380(b)(1)(vii)(A), should we apply the proposed Shared Savings Program scoring policy for excluded APP measures as described in section III.G.2.f. of this proposed rule?
- As noted above, providing ACOs with bonus points to their health equity adjusted quality performance score when ACOs' specialty clinicians report MVPs serves to encourage reporting of MVPs. Therefore, we do not intend to establish bonus points as a permanent policy. We seek comment on how long we should have bonus points in place in order to incentivize MVP reporting.
- Once specialists are reporting MVPs, overall aggregate specialty performance within an ACO could be assessed. We seek comment on if and how CMS should consider assessing overall specialty performance as part of the APP in the future.

We note that in section IV.A.1.b.(2) of this proposed rule, we included an RFI on how we can leverage MIPS policies to enable more Medicare beneficiaries to benefit from accountable care relationships within APMs and provide rigorous performance standards for those clinicians who report MVPs and remain in MIPS.

j. Proposal To Revise the Requirement To Meet the Case Minimum Requirement for Quality Performance Standard Determinations

(1) Background

We require ACOs to meet the case minimum requirement at § 414.1380 to determine the quality performance standard for ACOs in the first performance year of their first agreement period, for the eCQM/MIPS CQM incentive for performance year 2024, and for the extreme and uncontrollable circumstances policy (§ 425.512(a)(2), (a)(5)(i)(A)(2), (c)(3)).

Section 414.1380 includes policies related to all of MIPS scoring and is not specific to the Quality performance category. Further, the phrase ''case minimum'' is mentioned in multiple paragraphs at § 414.1380. The broad reference to § 414.1380 under § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3) does not specify which paragraph at § 414.1380 is applicable when applying case minimum for purposes of determining an ACO's quality performance standard. We believe that the references to meeting the case minimum requirement at § 414.1380 in the context of determining an ACO's quality performance standard under § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3) is not sufficient in describing our policy's intent, which is to apply the MIPS Quality performance category scoring policies as described at § 414.1380(b)(1) in determining the ACO quality performance standard.

(2) Proposed Revisions

In order to alleviate confusion regarding the reference to case minimum in determining the ACO quality performance standard, for performance year 2024 and subsequent performance years, we propose to replace the references to meeting the case minimum requirement at § 414.1380 from § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3) with the requirement that the ACO must receive a MIPS Quality performance category score under § 414.1380(b)(1) in order to meet the quality performance standard. This proposal would correct the purpose of our reference to case minimums by incorporating all of the applications of case minimums in the MIPS Quality performance category scoring policies in our policies to determine an ACO's quality performance standard under the Shared Savings Program. For example, under current policy at § 414.1380(b)(1)(i)(A)(2)(ii) in performance year 2024, if an ACO does not meet the case minimum requirement on an administrative claims-based measure, that measure would be excluded from the ACO's MIPS Quality performance category measure achievement points (numerator) and total available measure achievement points (denominator). If the ACO in this example meets the data completeness requirement at § 414.1340 for the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs and administers a CAHPS for MIPS survey, the ACO would receive a MIPS Quality performance category score. The resulting MIPS Quality performance category score in this example would be used to determine the ACO's quality performance standard under the Shared Savings Program.

All ACOs that participated in the Shared Savings Program were affected by an extreme and uncontrollable circumstance as described at § 425.512(c)(1) for performance years 2021, 2022, and 2023 due to the COVID–19 public health emergency. We believe that any unintended impact of meeting the case minimum requirement at § 414.1380 in evaluating an ACO's quality performance standard for performance years 2021, 2022, and 2023

was mitigated by the application of the extreme and uncontrollable circumstance policy. Specifically, it is not our intent to exclude an ACO who received a MIPS Quality performance category score, but reported less than 20 cases on any measure(s) in the APP measure set from achieving the quality performance standard under § 425.512(a)(2), (a)(5)(i)(A)(2), and (c)(3), if that ACO is otherwise eligible to meet the quality performance standard.

Separately, we propose to address a gap in the current rule regarding the ''minimum beneficiary sampling requirement'' at § 414.1380(b)(1)(vii)(B). This provision provides for a 10-point reduction in the total available measure achievement points for MIPS eligible clinicians that submit five measures or fewer and register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirement. As the case minimum is not applicable to the CAHPS for MIPS survey, we did not intend to preclude ACOs that do not meet the minimum beneficiary sampling requirement to field a CAHPS for MIPS survey from meeting the Shared Savings Program quality performance standard or the alternative quality performance standard. We propose revisions to the following regulation text sections:

- At § 425.512(a)(2)(ii) and (iii), we propose to replace the phrase ''case minimum requirement at § 414.1380 of this subchapter'' with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.''

Additionally, we propose to replace the phrase ''CAHPS for MIPS survey'' with the phrase ''CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).'' To read as follows: For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO would meet the quality performance standard under the Shared Savings Program, if:

++ For performance year 2024, the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.

++ For performance year 2025 and subsequent performance years, the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the three eCQMs/MIPS CQMs/Medicare CQMs and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter

- At § 425.512(a)(5)(i)(A)(2), we propose to remove the phrase ''and the case minimum requirement at § 414.1380 of this subchapter.'' As follows: For performance year 2024, under the eCQM/MIPS CQM reporting incentive, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, as applicable, if the ACO: (1) meets the data completeness requirement at § 414.1340 for all three eCQMs/MIPS CQMs; (2) achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and (3) achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

++ We are not including a requirement under § 425.512(a)(5)(i)(A)(2) for the ACO to receive a MIPS Quality performance category score under § 414.1380(b)(1). As described at § 414.1380(b)(1)(vii), the MIPS Quality performance category score is the sum of all the measure achievement points divided by the sum of total available measure achievement points for the quality performance category. Therefore, we do not believe that it would be appropriate to require an ACO to receive a MIPS Quality performance category score in determining whether the ACO met the Shared Savings Program quality performance standard based on measure-level performance (such as in the case of the eCQM/MIPS CQM reporting incentive).

- At § 425.512(c)(3), we propose to remove the phrase ''case minimum'' for performance 2024 and subsequent performance years and replace with the phrase ''receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter.'' To read as follows: Under the extreme and uncontrollable circumstances policy, for performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS would use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

We are proposing to revise § 425.512(a)(5)(iii)(A) and (B) to read as follows:

- For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

- For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter) under the APP.

Additionally, we propose to add clarifying language to the proposed redesignated paragraph (b)(2) of § 425.512 on calculating an ACO's health equity adjusted quality performance score as follows:

- For performance year 2024 and subsequent performance years, CMS will calculate the ACO's health equity adjusted quality performance score as the sum of: the ACO's MIPS Quality performance category score for all measures in the APP measure set, and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(3) of this section, to which the sum of these values may not exceed 100 percent, if the following requirements are met: (1) The ACO reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set; (2) meets the data completeness requirement at § 414.1340 for the three eCQMs/MIPS CQMs/Medicare CQMs; and (3) administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)).

3. Determining Beneficiary Assignment Under the Shared Savings Program

a. Proposed Modifications to the Step-Wise Assignment Methodology and Approach To Identifying the Assignable Beneficiary Population

(1) Background

(a) Background on Assignment Methodology

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO and, in the case of performance years beginning on or after January 1, 2019, services provided by a FQHC or RHC. As we have explained in earlier rulemaking, the term ''assignment'' for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive covered services. In the context of the Shared Savings Program, ''assignment'' refers to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of certain primary care services from physicians and other health care practitioners associated with a specific ACO so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care.[151]

The regulations governing the assignment methodology under the Shared Savings Program are in 42 CFR part 425, subpart E. Under claims-based assignment, we determine a Medicare FFS beneficiary is assigned to an ACO if the beneficiary meets the criteria in § 425.401(a) to be eligible for assignment to an ACO, and the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology specified in §§ 425.402 and 425.404. Section 425.402 specifies a step-wise assignment methodology for determining an ACO's assigned beneficiary population based on beneficiaries' use of primary care services. In accordance with § 425.402(b)(1), as a ''pre-step'' in the two-step claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service furnished by a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or has one of the primary specialty designations specified in § 425.402(c). This pre-step is designed to satisfy the statutory requirement under section 1899(c)(1) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians participating in the ACO. Beneficiaries who meet the pre-step requirement are then assigned to an ACO through either one of two steps specified in § 425.402(b)(3) and (b)(4).

Under the first step of the assignment process, a beneficiary who is eligible for assignment and meets the pre-step requirement is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in the ACO are greater than the allowed charges for primary care services furnished during the assignment window by primary care physicians, nurse practitioners, physician assistants, or clinical nurse specialists who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN. The second step of the assignment methodology applies to the remainder of the beneficiaries who are eligible for assignment and meet the pre-step requirement, who have not had a primary care service rendered during the assignment window by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by physicians who are ACO professionals with specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished during the assignment window by physicians with such specialty designations who are ACO professionals in any other ACO, or who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

The Shared Savings Program step-wise assignment process is offered in two similar, but distinct, claims-based assignment methodologies, prospective assignment and preliminary prospective assignment with retrospective reconciliation. Consistent with the requirements of section 1899(c)(2)(A) of the Act, we offer all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning on July 1, 2019. We use the same step-wise assignment methodology under § 425.402 to assign beneficiaries to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation.

In the June 2015 final rule (80 FR 32699) we finalized the definition of ''assignment window'' under § 425.20 to mean the 12-month period used to assign beneficiaries to an ACO. As described in the December 2018 final rule, the assignment window for ACOs under prospective assignment is a 12-month period offset from the calendar year (for example, October through September preceding the calendar year), while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year (83 FR 67861). Operationally, in determining beneficiary assignment for each performance year and benchmark year, we identify allowed charges for services billed under the HCPCS and CPT codes included in the applicable definition of primary care services under § 425.400(c), and according to the step-wise assignment methodology specified in subpart E of the Shared Savings Program's regulations, during all months of the 12-month period of the assignment window.

The step-wise assignment methodology was initially established with the November 2011 final rule and was modified through subsequent rulemaking. For instance, with the June 2015 final rule, we modified the approach to include claims for primary care services furnished by non-physician practitioners (nurse practitioners, physician assistants, and clinical nurse specialists) in step one of the assignment methodology rather than in step two, and to exclude services provided by certain physician specialties from step two of the assignment process. We refer readers to the November 2011 final rule and the June 2015 final rule for a discussion of the relevant background and related considerations (see 76 FR 67853 through 67858, and 80 FR 32748 through 32755). Generally, as we have previously explained in rulemaking, the step-wise assignment methodology maintains the statutory requirement to conduct claims-based beneficiary assignment based on beneficiaries' utilization of physician primary care services, recognizing the necessary and appropriate role of certain specialists in providing primary care services, such as

[151] See for example, 76 FR 67851, and 83 FR 67863.

in areas with primary care physician shortages (see, for example, 76 FR 67853 through 67855; see also 80 FR 32748 and 32754). Further, including services furnished by nurse practitioners, physician assistants, and clinical nurse specialists in determining where a beneficiary has received the plurality of primary care services in step one of the assignment methodology helps ensure that a beneficiary is assigned to the ACO whose ACO participants are actually providing the plurality of primary care for that beneficiary, and thus, should be responsible for managing the patient's overall care, or is not assigned to any ACO if the plurality of the beneficiary's primary care is furnished by practitioners in a non-ACO entity (see, for example, 80 FR 32748).

Various Shared Savings Program operations are based on the ACO's assigned population, or consider the size of the ACO's assigned population, which are summarized as follows:

- Within the Shared Savings Program's financial methodology:

++ CMS determines benchmark and performance year expenditures based on the ACO's assigned population as specified under subpart G of the regulations.

++ CMS determines the counties to include in the ACO's regional service area based on the ACO's assigned population (refer to definition of ACO's regional service area in § 425.20), and uses the ACO's assigned population in determining the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO (see §§ 425.601(a)(5)(v) and 425.652(a)(5)(v)) which is applied in calculating the two-way blend of national and regional growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(iv) and 425.652(a)(5)(iv) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b) and 425.652(b)(2). CMS also uses the ACO's regional service area to determine the regional adjustment to the ACO's historical benchmark according to § 425.656.

++ CMS considers the proportion of the ACO's assigned beneficiary population that is dually eligible for Medicare and Medicaid and the difference between the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types and when calculating the offset factor applied to negative regional adjustments (see § 425.656(c)(4)).

++ CMS considers the size of the ACO's assigned population in calculating the proration factor when determining the ACO's eligibility for the prior savings adjustment (see § 425.658(b)(3)) as well as in determining the minimum savings rate (MSR)/minimum loss rate (MLR) for ACOs that select the option to have their MSR/MLR calculated based on the number of beneficiaries assigned to the ACO (refer to § 425.605(b)(2)(i)(C) (BASIC track) and § 425.610(b)(1)(iii) (ENHANCED track)).

++ CMS determines average prospective HCC risk scores for assigned beneficiaries for purposes of adjusting assigned beneficiary expenditures for severity and case mix (refer to §§ 425.601(a)(3), 425.601(a)(10), 425.605(a)(1), 425.610(a)(2), 425.652(a)(3), and 425.652(a)(10)), adjusting for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area according to §§ 425.601(a)(8)(i)(C) and 425.656(b)(3), and adjusting the flat dollar amount ACPT for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population according to § 425.660(b)(4).

- In determinations related to an ACO's eligibility for participation for the Shared Savings Program:

++ CMS determines expenditures based on the ACO's assigned population when identifying if the ACO is a high revenue or low revenue ACO (as defined under § 425.20).

++ CMS considers whether an ACO meets the requirement to have at least 5,000 Medicare FFS assigned beneficiaries (see § 425.110).

++ CMS uses the ACO's number of assigned beneficiaries in calculating and recalculating the amount of the repayment mechanism required for ACOs participating under a two-sided model (see § 425.204(f)).

- For ACOs eligible to receive advance investment payments (see § 425.630(b)), CMS considers the size of the ACO's assigned population and the risk factors-based score of those beneficiaries in determining the quarterly payment amount (see § 425.630(f)).

- For ACOs that meet the reporting requirements for receiving a health equity adjusted quality performance score (see § 425.512(b)), CMS considers the proportion of the ACO's assigned beneficiary population that is underserved in determining the ACO's health equity adjustment bonus points (see § 425.512(b)(2)(iv)).

- For ACOs affected by an extreme and uncontrollable circumstance, CMS considers the proportion of the ACO's assigned beneficiaries residing in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance in determining the ACO's quality score (see § 425.512(c)(1)(i)). CMS considers the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance in determining the amount of shared losses owed by ACOs under a two-sided model (refer to §§ 425.605(f)(1) and 425.610(i)(1)).

- For ACOs that have established a beneficiary incentive program, beneficiaries assigned to an ACO who receive a qualifying service are eligible to receive an incentive payment (see § 425.304(c)(3)(ii) through (iv)).

- In accordance with the Shared Savings Program regulations under subpart H, CMS provides ACOs with certain aggregate reports and beneficiary-identifiable claims data on the ACO's assigned beneficiary population.

Further, a non-claims-based process for voluntary alignment applies to all Shared Savings Program ACOs and is used to supplement claims-based assignment. Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. In the November 2018 final rule (83 FR 59959 through 59964), we finalized changes to the beneficiary voluntary alignment policies CMS previously established to implement the requirements under section 1899(c)(2)(B) of the Act (refer to § 425.402(e), as revised). In the November 2018 final rule (83 FR 59964), we revised the requirements related to primary care services and practitioner specialties previously established for the voluntary alignment process. As a result of this change, a voluntarily aligned beneficiary is no longer required to receive a primary care service from an ACO professional to be assigned to the ACO in which the beneficiary's designated primary care clinician is participating. Additionally, the revision established that a beneficiary can be voluntarily aligned to an ACO based on their selection of any ACO professional as their primary clinician, regardless of the ACO professional's specialty and including nurse practitioners, physician assistants, and clinical nurse specialists. As specified in § 425.402(e)(1), and subject to § 425.402(e)(2), assignment under voluntary alignment supersedes

any assignment that otherwise may have occurred under claims-based assignment.

(b) Background on Identification and Uses of the Assignable Beneficiary Population Under the Shared Savings Program

To identify the assignable beneficiary population, which is used in program financial calculations, we apply a similar logic as is used to identify the Medicare beneficiaries who can be assigned to an ACO in the pre-step to the claims-based assignment methodology (see, for example, 81 FR 5843, and 81 FR 37985). In the June 2016 final rule (81 FR 37950), we finalized policies to use the assignable beneficiary population (a subset of the larger population of Medicare FFS beneficiaries) as the basis of certain calculations that had previously been based on the overall Medicare FFS population, including expenditures used to trend and update ACOs' historical benchmarks and to establish the truncation thresholds used in expenditure calculations. In the June 2016 final rule, we finalized the definition of ''assignable beneficiary'' under § 425.20 to mean a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). We specified that the assignable population used to calculate national and regional benchmarking factors was to be identified using the 12-month calendar year assignment window corresponding to the benchmark or performance year for all ACOs, regardless of assignment methodology which applied to the ACO, which at that time was determined by an ACO's track (see 81 FR 37985 through 37988). We explained our belief that using assignable beneficiaries across all program calculations based on national and regional FFS expenditures would result in factors that are generally more comparable to ACO expenditures than factors based on the overall Medicare FFS population, which can include non-utilizers of health care services and other beneficiaries not eligible for assignment (see, for example, 81 FR 5843 and 5844).

In the CY 2023 PFS final rule (87 FR 69929 through 69932), we finalized a modification to this policy, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, to calculate risk-adjusted regional expenditures and the share of assignable beneficiaries assigned to an ACO using county-level values based on the assignable population identified using an assignment window that is consistent with the ACO's assignment methodology selection for the applicable performance year. (Refer to §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), and 425.654(a)(1)(i).) Under this approach, for ACOs selecting prospective assignment, we will use an assignable population of beneficiaries that is identified based on the offset assignment window (for example, October through September preceding the calendar year) and for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we will use an assignable population of beneficiaries identified based on the calendar year assignment window (87 FR 69930). We also specified in the CY 2023 PFS final rule that we would continue to compute all factors used in calculations that are based on the national assignable FFS population using an assignable population identified based on the calendar year assignment window. (Refer to 87 FR 69931.) For ACOs participating under agreement periods beginning on or after July 1, 2019, and before January 1, 2024, we will continue to identify the assignable population that is the basis for calculating national and regional factors using the 12-month period based on a calendar year, which aligns with the assignment window for preliminary prospective assignment with retrospective reconciliation, regardless of the ACO's assignment methodology. (See § 425.601. See also, 87 FR 69929, for a description of relevant background.)

The assignable beneficiary population is used in various calculations under the Shared Savings Program, including the following:

- CMS determines the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of truncating beneficiary expenditures in order to minimize variation from catastrophically large claims (see §§ 425.601(a)(4) and (c)(3), 425.605(a)(3), 425.610(a)(4)(ii), 425.652(a)(4), and 425.654(a)(3)).
- CMS determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county of an ACO's regional service area (see §§ 425.601(c) and 425.654(a)) for purposes of calculating the ACO's regional fee-for-service expenditures (see §§ 425.601(d) and 425.654(b)). CMS also determines the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO (see §§ 425.601(a)(5)(v) and 425.652(a)(5)(v)). The ACO's regional fee-for-service expenditures and the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO are used in the following calculations:
  - ++ Trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5) and 425.652(a)(5).
  - ++ Determine the blended growth rates used to update the benchmark according to §§ 425.601(b) and 425.652(b)(2).
  - ++ Determine the adjustment to the ACO's benchmark according to §§ 425.601(a)(8) and 425.652(a)(8).
- CMS determines national per capita fee-for-service expenditures for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.652(a)(8)(iv), and determining a flat dollar amount ACPT according to § 425.660(b)(3).
- CMS determines national growth rates for assignable beneficiaries that are used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and to determine the blended growth rates used update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).
- CMS determines average prospective HCC risk scores for assignable beneficiaries for purposes of adjusting county fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county according to §§ 425.601(c)(4) and 425.654(a)(4), calculating the regional adjustment to the historical benchmark by adjusting for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area according to §§ 425.601(a)(8)(i)(C) and 425.656(b)(3), and adjusting the flat dollar amount ACPT for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population according to § 425.660(b)(4).

(c) Concerns About Beneficiaries Excluded From the Current Assignment Methodology Based on the Pre-Step Requirement and Definition of an Assignable Beneficiary

CMS has established a goal that 100 percent of beneficiaries enrolled in Original Medicare be involved in a care relationship with accountability for

quality and total cost of care by 2030.[152] CMS has also established health equity as a top priority through our CMS Framework for Health Equity (2022–2032).[153] However, CMS believes that the assignment pre-step and definition of assignable beneficiary may create barriers for some beneficiaries otherwise eligible for assignment to be assigned to ACOs. Revising the pre-step and definition of assignable beneficiary thus represents an opportunity to expand the assigned and assignable populations.

ACOs and other interested parties have also raised concerns that the current pre-step and definition of assignable beneficiary create barriers for some beneficiaries to be assigned to ACOs. For example, in previous proposed rules, we have received input from commenters that the pre-step requirement, as implemented in the current assignment methodology, systematically excludes from assignment beneficiaries who only received primary care from nurse practitioners, physician assistants, and clinical nurse specialists. In response to the CY 2023 PFS proposed rule, a commenter noted that the current claims-based assignment methodology creates a barrier for nurse practitioners and their patients to participate in ACOs.[154]

Additional analysis by CMS has found that expanding the assignment methodology to allow more opportunities for beneficiaries to be assignable based on their receipt of primary care services provided by nurse practitioners, physician assistants, or clinical nurse specialists would reduce the barriers for underserved beneficiaries to be assigned to ACOs. As described in section III.G.3.a.(2)(d) of this proposed rule, we have observed from initial modeling of expanding the definition of an assignable beneficiary that such an approach could add to the national assignable population identified under current Shared Savings Program policies a population of beneficiaries that are more likely to be disabled, be enrolled in the Medicare Part D low-income subsidy (LIS), and reside in areas with higher ADI scores. The newly assignable population of beneficiaries also had a lower average prospective HCC risk score, lower total per capita-year spending, higher hospice utilization, and a higher mortality rate than the national assignable population under the current definition of an assignable beneficiary. Therefore, we believe that adjusting the assignment methodology within the flexibility available under the statute so that additional beneficiaries can be included in the population of beneficiaries assigned to ACOs participating in the Shared Savings Program, and modifying the definition of assignable beneficiary to include a broader population, would make meaningful steps toward greater health equity and align with priorities recently emphasized in our CMS Framework for Health Equity (2022–2032).[155]

(2) Proposed Revisions

(a) Overview of Proposed Revisions To Incorporate Use of an Expanded Window for Assignment

Section 1899(c)(1)(A) of the Act requires that claims-based assignment to ACOs be based on beneficiaries' utilization of primary care services furnished by ACO professionals who are physicians. We are proposing to use an expanded window for assignment in a new step three to the claims-based assignment process to identify additional beneficiaries for ACO assignment (described in section III.G.3.a.(2)(b). of this proposed rule), and we are proposing to modify the definition of ''assignable beneficiary'' to be consistent with this use of an expanded window for assignment to identify additional beneficiaries to include in the assignable population after application of the existing methodology (described in section III.G.3.a.(2)(c). of this proposed rule). We propose to add a new definition of ''Expanded window for assignment'' in § 425.20 to mean the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window (as defined under § 425.20) and the preceding 12 months.

To follow is a brief summary of the proposed uses of the expanded window for assignment, described in greater detail elsewhere within this section of this proposed rule. First, the proposed addition of a step three to the beneficiary assignment methodology would occur after the current steps one and two and would apply only to beneficiaries who do not meet the pre-step requirement but who received at least one primary care service during the proposed expanded window for assignment with an ACO professional who is a primary care physician or a physician who has one of the specialty designations included in § 425.402(c). Beneficiaries qualifying for step three would be assigned based on the plurality of allowed charges for primary care services during this expanded window for assignment. Second, the proposed revision to the definition of an assignable beneficiary would similarly include beneficiaries who receive at least one primary care service during the proposed expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). In combination with using the expanded window for assignment for identifying beneficiaries who received at least one primary care service from a primary care physician or a physician whose specialty designation is used in assignment, under both the proposed step three for assignment and proposed revised definition of an assignable beneficiary, we would continue to consider whether beneficiaries received at least one primary care service during the 12-month assignment window. We propose that these changes would be effective for the performance year beginning on January 1, 2025, and subsequent performance years.

A number of factors informed our consideration of the duration of the expanded window for assignment. We believe that a 24-month expanded window for assignment, as opposed to a longer period, would prioritize primary care services that were provided more recently. Through the proposed modifications to the assignment methodology and the definition of assignable beneficiary, we seek to better account for beneficiaries who may be receiving their primary care predominantly from non-physician practitioners during the 12-month assignment window, but who received care from a physician in the preceding 12 months, in recognition of the statutory requirement in section 1899(c) of the Act that claims-based assignment be based on receipt of primary care services from physicians who are ACO professionals. We believe that primary care services furnished by nurse practitioners, physician assistants, and

[152] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444*.

[153] Centers for Medicare & Medicaid Services, *The CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

[154] See comment letter from American Association of Nurse Practitioners, to Chiquita Brooks-LaSure, Administrator, CMS (September 6, 2022), available at *https://www.regulations.gov/comment/CMS-2022-0113-21927*.

[155] Centers for Medicare & Medicaid Services, *The CMS Framework for Health Equity 2022–2032* (April 2022), available at *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

clinical nurse specialists during the 12-month assignment window could reflect their work in clinical teams in collaboration with and under the supervision of physicians, and thereby represent a continuation of the beneficiary's primary care relationship with a physician from the previous year. Furthermore, use of a 24-month expanded window for assignment would build on experience we have gained and lessons learned from testing Medicare ACO initiatives by the Center for Medicare and Medicaid Innovation (Innovation Center), specifically from the use of a two-year beneficiary alignment period in the ACO Realizing Equity, Access, and Community Health (REACH) Model and the Next Generation ACO (NGACO) Model.[156]

We also believe it is timely to propose modifications to the definition of ''assignment window'' under § 425.20 for improved clarity and consistency with the programmatic applications of the assignment window. Under the existing definition, assignment window means the 12-month period used to assign beneficiaries to an ACO. However, under existing Shared Savings Program policies and under the proposed changes described in this section of this proposed rule, we use the term assignment window in referencing our identification of assignable beneficiaries. Therefore, we are proposing to modify the definition of assignment window to mean the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both.

We seek comment on proposed modifications to § 425.20, to revise the definition of ''assignable beneficiary,'' ''assignment window,'' and add a new definition of ''expanded window for assignment''.

[156] See, for example, CMS, Center for Medicare & Medicaid Innovation, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Operating Guide: Overview, available at *https://innovation.cms.gov/media/document/aco-reach-py2023-financial-op-guide* (refer to Appendix B, Beneficiary Alignment Procedures). See also, CMS, Center for Medicare & Medicaid Innovation, Next Generation ACO Model Benchmarking Methods (December 15, 2015), available at *https://innovation.cms.gov/files/x/nextgenaco-methodology.pdf* (refer to Appendix A, Next Generation ACO Model Alignment Procedures). In summary, under the ACO REACH Model and NGACO Model the alignment period consists of two alignment years. The first alignment year is the 12-month period ending 18 months prior to the start of the relevant performance year or base year. The second alignment year is the 12-month period ending 6 months prior to the start of the relevant performance year or base year.

(b) Proposed Revisions To Add a Step Three to the Beneficiary Assignment Methodology

For the performance year beginning on January 1, 2025, and subsequent performance years, we propose to revise the step-wise beneficiary assignment methodology, as described in § 425.402, to include a step three, which would utilize the proposed expanded window for assignment to identify additional beneficiaries for assignment among Medicare FFS beneficiaries who were not identified under the existing pre-step. Specifically, step three would identify all such beneficiaries not identified by the pre-step criterion specified in § 425.402(b)(1), who also meet the following criteria:

(1) Received at least one primary care service with a non-physician ACO professional (nurse practitioner, physician assistant, or clinical nurse specialist) in the ACO during the applicable 12-month assignment window.

(2) Received at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c) during the applicable 24-month expanded window for assignment.

A beneficiary meeting the aforementioned criteria would then be assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, non-physician ACO professionals, or physicians with specialty designations included in § 425.402(c) during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations included in § 425.402(c), nurse practitioners (as defined at § 410.75(b)), physician assistants (as defined at § 410.74(a)(2)), and clinical nurse specialists (as defined at § 410.76(b)) who are ACO professionals in any other ACO or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

Further, in order to be assigned to an ACO through the step-wise assignment methodology, a Medicare FFS beneficiary would continue to need to meet the eligibility criteria in § 425.401(a) for the 12-month assignment window, regardless of whether the beneficiary is assigned to an ACO in step one or two, or proposed step three. Under the proposed approach, beneficiaries who do not receive any primary care services during the assignment window would continue to be excluded from claims-based assignment as they are under the current assignment methodology. Beneficiaries who meet the pre-step based on a 12-month assignment window (as specified in § 425.402(b)(1)) but are not assigned to an ACO in steps one or two would also continue to not be assigned to an ACO as these beneficiaries would not be considered for assignment in step three. The proposed changes also would not change beneficiary voluntary alignment, which would continue to supersede claims-based assignment, as specified in § 425.402(e).

As specified in § 425.400(a)(3)(ii), beneficiaries who are prospectively assigned to an ACO will remain assigned to the ACO at the end of the benchmark or performance year, unless they meet any of the exclusion criteria under § 425.401(b). As a result, under claims-based assignment, a beneficiary prospectively assigned to an ACO is not eligible for assignment to a different ACO for the same benchmark or performance year.[157] We propose to continue to apply this approach for beneficiaries prospectively assigned at step one, step two, or proposed step three. In other words, a beneficiary who is assigned to an ACO based on prospective assignment through step one or two or proposed step three would remain assigned to that ACO for the benchmark or performance year (unless they meet any of the exclusion criteria under § 425.401(b)). Under this approach, a beneficiary prospectively assigned to an ACO for a benchmark or performance year would not be assigned to another ACO under prospective assignment or to an ACO under preliminary prospective assignment with retrospective reconciliation, even if the other ACO provides the plurality of the beneficiary's primary care services during the relevant benchmark or performance year.

The use of a 24-month expanded window for assignment would also require changes to the timeframe for which we recognize additional primary care service codes related to the COVID–19 Public Health Emergency (PHE), as outlined in § 425.400(c)(2). Under § 425.400(c)(2), we use certain additional primary care service codes in

[157] See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*(see section 2.3.2.2, ''Prospective Assignment'').

determining beneficiary assignment under § 425.400(c)(1) when the assignment window for a benchmark or performance year includes any month(s) during the COVID–19 PHE (as defined in § 400.200). In accordance with § 425.400(c)(2)(ii), the additional primary care service codes are applicable to all months of the assignment window, when the assignment window includes any month(s) during the COVID–19 PHE, with the exception of certain additional CPT codes (99441, 99442, and 99443) which we use in determining assignment until they are longer payable under Medicare FFS payment policies (as specified under § 425.400(c)(2)(i)(A)(2)). We refer readers to discussions in earlier rulemaking for the development of this policy, including 85 FR 84748 through 84755, 85 FR 84791 through 84793, and 86 FR 65276. We propose to modify the regulations at § 425.400(c)(2)(i) and (ii) to incorporate references to the expanded window for assignment, such that we would apply the additional primary care service codes to all months of the assignment window or applicable expanded window for assignment when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID–19 PHE. These proposed changes are necessary to capture the additional codes related to the COVID–19 PHE when using the expanded window for assignment in determining assignment for a benchmark or performance year.[158]

The proposed use of an expanded window for assignment in an enhanced step-wise assignment methodology would result in a greater overall number of beneficiaries assigned to ACOs. All beneficiaries who are assigned to an ACO under the current methodology would continue to be assigned to an ACO under the proposed methodology. Under the proposed methodology, a beneficiary who does not meet the current pre-step requirement would also be eligible to be assigned to an ACO if they (a) received at least one primary care service from a nurse practitioner, physician assistant, or clinical nurse specialist who is an ACO professional in the ACO during the applicable assignment window and (b) received at least one primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the applicable expanded window for assignment.

Under proposed changes, the 12-month assignment window would continue to represent the period used to identify allowed charges for primary care services received from ACO professionals and analogous practitioners not participating in an ACO, for purposes of claims-based beneficiary assignment during steps one and two. Thus, most beneficiaries currently assigned to an ACO under the existing assignment methodology would continue to be assigned to the same ACO under the proposed changes. We anticipate that only a very small share of beneficiaries would be assigned to a different ACO under the proposed assignment methodology, and any change in ACO assignment would be due to the operational order in which assignment is run and the precedence of prospective assignment over preliminary prospective assignment with retrospective reconciliation. Specifically, there may be a small share of beneficiaries who would be prospectively assigned to an ACO under the proposed step three for prospective assignment that differs from the retrospective ACO the beneficiary is currently assigned to under steps one or two for preliminary prospective assignment with retrospective reconciliation. This precedence of prospective assignment follows the current assignment methodology, which currently assigns beneficiaries via steps one and two of prospective assignment to an ACO that may be different than the ACO to which the beneficiary would have been assigned via steps one or two if assigned to an ACO under preliminary prospective assignment with retrospective reconciliation. For the average retrospective ACO, the share of assigned beneficiaries affected by this precedence of prospective assignment has historically been very small, approximately 1.3 percent from 2018 through 2021.

The proposed addition of step three would add a population of otherwise omitted beneficiaries by using the expanded window for assignment to identify the required physician visit with an ACO professional and to determine the plurality of allowed charges for primary care services. Functionally, the beneficiaries who would be newly assigned are beneficiaries who received a primary care service from an ACO professional who is a primary care physician (as defined under § 425.20) or who has one of the specialty designations included in § 425.402(c) in the 12-month period prior to the assignment window and received a primary care service from a nurse practitioner (as defined at § 410.75(b)), a physician assistant (as defined at § 410.74(a)(2)), or a clinical nurse specialist (as defined at § 410.76(b)) during the assignment window. Notably, the proposed step 3 would continue to be consistent with section 1899(c)(1)(A) of the Act, because a beneficiary would have to have received a primary care service from a primary care physician or physician with a specialty used in assignment who is an ACO professional in the ACO during the expanded window for assignment to be eligible for assignment to the ACO.

Similar to any other change that affects beneficiary assignment, the proposed use of an expanded window for assignment in a step three could impact downstream aspects of the Shared Savings Program that rely on the assigned population, including the following potential effects:

- Larger populations of assigned beneficiaries could contribute to more ACOs meeting minimum size requirements to participate in the program.
- A larger assigned population would result in lower minimum savings rates for ACOs subject to a variable minimum savings rate (that is, ACOs in a one-sided risk model on the BASIC track's glide path or ACOs in a two-sided risk model that elected a variable minimum savings rate). Lower minimum savings rates reflect a lower threshold for ACOs to meet in order to share in savings. Similarly, a larger assigned population would result in a lower minimum loss rate for ACOs in a two-sided risk model with a variable minimum loss rate, which reflects a lower threshold for two-sided risk ACOs to meet before they must share in losses.
- A larger assigned population would enable higher performance payment limits, which are based on a percentage of an ACO's total benchmark expenditures. As an ACO's assigned beneficiary population increases, so too do the ACO's total benchmark expenditures. Because the maximum shared savings an ACO can earn is determined as a percentage of total benchmark expenditures, a larger assigned population would result in a higher performance payment limit. Similarly, a larger assigned population

[158] See, for example, HHS Secretary Xavier Becerra Statement on End of the COVID–19 Public Health Emergency (May 11, 2023), available at *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html*. See also Letter to U.S. Governors from HHS Secretary Xavier Becerra on renewing COVID–19 Public Health Emergency (PHE), available at *https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html* (specifying the U.S. Department of Health and Human Services is planning for the COVID–19 PHE to end on May 11, 2023).

would result in larger loss sharing limit for ACOs in two-sided risk models because loss sharing limits are also determined as a percentage of aggregate benchmarks.

- A larger assigned population could affect an ACO's revenue status as the ACO's ACO participants' total Medicare Parts A and B fee-for-service (FFS) revenue would not change but the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures would increase. In other words, revenue-to-expenditure ratios would decrease for ACOs that receive a larger assigned beneficiary population. Compared to the current assignment methodology, the proposed assignment methodology change could result in some ACOs being identified as low revenue instead of high revenue. As a result, other program elements tied to revenue status could then be affected by the proposed changes, specifically an ACO's eligibility for Advance Investment Payments.
- Changes in the assigned population could directly affect ACOs' average risk scores, mix of beneficiaries across enrollment types, regional service area, and total expenditures during benchmark and performance years.

Expected impacts on several other program elements would depend on differences in the changes observed for beneficiaries added to the assignable population versus beneficiaries added to the ACO's assigned beneficiaries. For example, the impact of the proposed change to the assignment methodology on ACO performance would depend in part on the difference in spending levels and trends between those beneficiaries added to the assignable population, nationally and within an ACO's regional service area, versus those beneficiaries added to the ACO's assigned beneficiary population. The data shared with ACOs on their assignable and assigned beneficiaries would change under the proposed policy as the population of assignable and assigned beneficiaries changes.

We propose modifications to subpart E of the Shared Savings Program regulations to specify the revised beneficiary assignment methodology. We propose to specify the new step three in a new provision at § 425.402(b)(5). We also propose technical and conforming changes to incorporate the revised methodology. We propose to amend § 425.402(b)(1), describing the existing pre-step of the assignment methodology that would remain applicable for step one and step two, to refer to the identification of all beneficiaries who had ''at least one primary care service *during the applicable assignment window* with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in [§ 425.402(c)]'' (emphasis added to reflect revised text). In § 425.402(c), which indicates the primary specialty designations used in assignment, we propose to specify that the listed specialties would be considered for ACO professionals in step two (as described in § 425.402(b)(4)) and the proposed step three (which would become a new provision at § 425.402(b)(5)) of the assignment methodology. In § 425.400(a)(2)(ii), which generally describes quarterly updates to preliminary prospective assignment with retrospective reconciliation, we propose to specify that assignment would be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404. Lastly, in § 425.400(a)(3)(i), which generally describes prospective assignment of beneficiaries to ACOs at the beginning of each benchmark or performance year, we propose to amend the reference that specifies that we base prospective assignment on the beneficiary's use of primary care services in the most recent 12 months for which data are available, to specify instead the beneficiary's use of primary care services in the most recent 12 months or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404.

(c) Proposed Revisions to the Definition of an Assignable Beneficiary

Consistent with the previously described proposal to use an expanded window for assignment in an enhanced step-wise assignment methodology, we are proposing to revise the definition of Assignable beneficiary in § 425.20 to include additional beneficiaries who would be identified using the expanded window for assignment. Under this proposal, we would continue to utilize the criterion in the existing definition, under which assignable beneficiary means a Medicare FFS beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). Further, for the performance year beginning January 1, 2025 and subsequent performance years, we propose that a Medicare fee-for-service beneficiary who does not meet this requirement but who meets both of the following criteria would also be considered an assignable beneficiary:

- Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).
- Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is a nurse practitioner (as defined at § 410.75(b)), physician assistant (as defined at § 410.74(a)(2)), or a clinical nurse specialist (as defined at § 410.76(b)).

The proposed use of an expanded window for assignment would result in a greater number of beneficiaries included in the assignable population. All beneficiaries who are currently assignable would continue to be assignable under the proposed revisions to the definition of an assignable beneficiary. Under the proposed definition, beneficiaries who do not receive any primary care services during the assignment window would continue to be excluded from the population of assignable beneficiaries, just as they are excluded in the current definition of an assignable beneficiary. In other words, the 12-month assignment window would continue to represent the timeframe within which beneficiaries must receive at least one primary care service to be identified as an assignable beneficiary. Moreover, to identify a broader assignable population under this proposed approach, we believe it is important to consider the criterion for the beneficiary to have received a primary care service during the 12-month assignment window to be met through a service furnished from a non-physician practitioner (nurse practitioner, physician assistant, and clinical nurse specialist), or from a primary care physician or a physician who has one of the specialty designations included in § 425.402(c) (as is required under the current definition).

The proposed approach to expanding the assignable beneficiary population could impact downstream aspects of the Shared Savings Program that rely on the assignable population, including the following effects:

- Changes in the distribution of expenditures among the national assignable population could affect the thresholds used to truncate expenditures.

• Changes in average per capita expenditures and risk scores among assignable beneficiaries in a given benchmark year could affect the average risk-adjusted spending within ACOs' regional service areas, which could affect regional adjustments.

• Differential changes in average per capita expenditures and risk scores over time could affect trend and update factors that are based on changes in expenditures for the national assignable population and in the risk-adjusted expenditures for the population of assignable beneficiaries in an ACO's regional service area.

• Changes in average prospective HCC risk scores for the national assignable population could affect the factors used to renormalize risk scores each benchmark and performance year and to risk-adjust the flat-dollar ACPT amounts.

• Changes in the number of assignable beneficiaries across ACO regional service areas could affect ACOs' market shares, which determine the weights used for blending the national and regional benchmark trend and update factors.

• Changes in the level of national fee-for-service expenditures for the assignable population could affect the caps applied to the regional adjustment and prior savings adjustment to the historical benchmark and the calculation of the flat-dollar ACPT amount.

Under the current regulations, the time period we use to identify the assignable population that will be used to calculate different factors used in program financial calculations depends on whether it is a national or regional factor, the start date of an ACO's agreement period and, in some cases, an ACO's selected assignment methodology. Under the proposed revised definition of assignable beneficiary, for all ACOs (regardless of agreement period start date), for the performance year beginning on January 1, 2025, and subsequent performance years, for benchmark year and performance year factors based on the national assignable population, we would identify the assignable population using the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window, which aligns with the assignment window for preliminary prospective assignment with retrospective reconciliation, and the preceding 12 months. We note that under this proposal we would also use the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window and the preceding 12 months when identifying the assignable population for regional factors for performance year 2025 and subsequent years for use in calculations for ACOs that are continuing in agreement periods that began before January 1, 2024.

For ACOs participating in agreement periods beginning on January 1, 2024, and in subsequent years, for performance year 2025 and in subsequent years for regional factors, we would identify the assignable population using the 24-month expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii). That is, for ACOs selecting preliminary prospective assignment with retrospective reconciliation, we would use the 24-month expanded window for assignment comprised of the 12-month calendar year assignment window and the preceding 12 months. For ACOs selecting prospective assignment, the 24-month expanded window for assignment would be comprised of the 12-month, offset assignment window plus the preceding 12 months. For example, we would use October 1, 2022, to September 30, 2024, as the 24-month expanded window for assignment to identify the assignable population for performance year 2025 for ACOs under prospective assignment.

We propose technical and conforming changes to provisions in subpart G of the Shared Savings Program regulations that refer to the assignment window used to identify the assignable beneficiary population in order to incorporate references to the proposed approach to using an expanded window for assignment in identifying the assignable population for performance year 2025 and in subsequent years. The regulations establishing the benchmarking methodology for ACOs with agreement periods beginning before January 1, 2024, do not directly reference the assignment window, and thus would not require conforming changes. However, there are benchmarking methodology provisions for ACOs with agreement periods beginning on January 1, 2024, and in subsequent years that directly refer to the assignment window. Thus, we propose to amend these provisions to specify that the assignable population would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii):

• In §§ 425.652(a)(5)(v)(A) and (b)(2)(iv)(A), provisions on calculating the county-level share of assignable beneficiaries who are assigned to the ACO for each county in the ACO's regional service area for purposes of calculating the blended national-regional growth rates used in trending and updating the benchmark (respectively).

• In the provision on redetermination of the regional adjustment for the second or each subsequent performance year during the term of the agreement period in § 425.652(a)(9)(ii).

• In the provision on the calculation of average county FFS expenditures for assignable beneficiaries in each county in the ACO's regional service area in § 425.654(a)(1)(i).

• In the provision on adjusting for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable beneficiary population for the ACO's regional service area for BY3, in calculating average per capita expenditures for the ACO's regional service area, in § 425.656(b)(3).

Similarly, we also propose to specify in the proposed new provision at § 425.655(b)(1) that the assignable population that would be used to calculate average county prospective HCC and demographic risk scores for purposes of calculating the proposed regional risk score growth cap adjustment factor (refer to section III.G.4.b. of this proposed rule) would be identified for the relevant benchmark year or the performance year (as applicable) using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

We seek comment on our proposed modifications to the definition of assignable beneficiary in § 425.20. We also seek comment on our proposed technical and conforming changes to references to the identification of assignable beneficiaries in subpart G of the Shared Savings Program regulations, as well as in the proposed new regulation at § 425.655 (on calculating the regional risk score growth cap adjustment factor), to incorporate the use of the assignment window or expanded window for assignment in identification of the assignable beneficiary population.

(d) Simulations To Understand the Potential Effect of Proposed Changes

To understand the potential impact of using an expanded window for assignment in a proposed step 3 of the claims-based assignment methodology, we simulated using the proposed definition for an assignable beneficiary and proposed step 3 using the set of ACOs and data for performance year (PY) 2021. To simplify the analysis, this simulation used CY 2021 as the assignment window. Thus, the expanded window for assignment spanned from January 1, 2020, through December 31, 2021. We used a calendar year basis because we do not expect the impact of the proposed changes to meaningfully differ between retrospective and prospective assignment windows, the latter of which uses an offset window. In this analysis, the national assignable population included a total of 26.2 million beneficiaries based on the current methodology. The simulation applying the proposed policies then added 762,156 newly assignable beneficiaries, growing the national assignable population by about 2.9 percent. For additional analysis on estimated impacts, we also refer commenters to the Regulatory Impact Analysis in section VII.E. of this proposed rule. We seek comment on the proposed approach discussed in this proposed rule and the potential effects of the proposed approach, including its effects modeled in the aforementioned simulation and its effects in other scenarios that might be considered by commenters. We anticipate continuing additional simulations on the effect of the proposed changes to the assignment methodology to further inform our understanding of the potential impacts of the proposal, and we are planning to publish results from such additional simulations in the final rule.

Simulation results suggest that an expanded window for assignment may increase access to accountable care for underserved beneficiaries. Relative to the national assignable population as determined under the current assignment methodology, the group of added beneficiaries from the expanded window for assignment simulation had a larger share of beneficiaries with disabled Medicare enrollment type, resided in areas with slightly higher average Area Deprivation Index (ADI) national percentile rank (a measure of neighborhood socioeconomic disadvantage), and had a larger share with any months of Medicare Part D LIS enrollment (refer to Table 30).

TABLE 30: Selected Characteristics of Beneficiaries Added to the National Assignable Population for PY 2021 through the Expanded Window for Assignment Simulation

	National Assignable Population Under Current Assignment Methods	Added to the National Assignable Population in the Simulation	National Assignable Population Under the Simulation
Total Beneficiaries	26,169,153	762,156	26,931,309
Total Person Years[1]	24,900,013	694,132	25,594,145
Share of Person Years by Medicare Enrollment Type			
End Stage Renal Disease (ESRD)	0.9%	1.0%	0.9%
Disabled	11.1%	15.2%	11.2%
Aged/Dual	8.5%	7.6%	8.5%
Aged/Non-Dual	79.5%	76.3%	79.4%
Mean ADI National Percentile Rank[2]	43.2	46.5	43.3
Share of beneficiaries with at least one month of Medicare Part D LIS Enrollment	20.4%	24.0%	20.5%

[1] This approach is consistent with calculation of ACO assigned beneficiary person years as described in the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version # 11, January 2023) available *at https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*. Note that calculations of person years exclude months associated with episodes of care for treatment of COVID-19. Refer to Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications of Policies to Address the Public Health Emergency for COVID-19 (December 2020) available at: https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf.

[2] Mean ADI National Percentile Rank was calculated as a weighted mean, weighted by person years, among beneficiaries with non-missing ADI percentile.

Simulation results also suggest that using a 24-month expanded window for assignment in proposed step 3 of the claims-based assignment methodology would increase access to accountable care among beneficiaries with Medicare coverage for part of a year (such as beneficiaries who die during the performance year). The group of added assignable beneficiaries in the simulation previously described had a lower average prospective HCC risk score, lower total per capita spending in CY 2021, higher hospice utilization, and a higher mortality rate when compared to assignable beneficiaries determined using the current definition of assignable beneficiary and assignment

methodology. These results suggest that beneficiaries who would be added to the assignable population under the proposed changes may benefit from greater care coordination through ACOs.

(e) Implementation of Proposed Revisions

We are proposing that the expanded window for assignment and revised step-wise assignment methodology would be applicable to all ACOs for the performance year beginning on January 1, 2025, and in subsequent years. For example, for a calendar year assignment window that runs from January 1, 2025, through December 31, 2025, the expanded window for assignment would run from January 1, 2024, through December 31, 2025. For an offset assignment window that runs from October 1, 2023, through September 30, 2024, the expanded window for assignment would run from October 1, 2022, through September 30, 2024. Consistent with how we have implemented previous changes to the Shared Savings Program assignment methodology, we would use the new methodology each time assignment is determined for a given benchmark or performance year and, as applicable, to determine the eligibility of ACOs applying to enter into or renew participation in the Shared Savings Program. For example, applicant eligibility for PY 2024 will be determined during CY 2023. We would not be able to review public comments and decide whether to finalize the proposed changes in sufficient time to apply the expanded window for assignment and revised methodology for PY 2024 applications. Additionally, we anticipate that the proposed revised approach, if finalized, would require significant operational changes to the Shared Savings Program assignment methodology, which would take time to prepare in advance of initial use of the approach during the application process. For these reasons, we would not be able to apply the expanded window for assignment and revised step-wise beneficiary assignment methodology for the performance year starting on January 1, 2024, and we are proposing to apply this change beginning with the performance year starting on January 1, 2025.

We would apply the proposed revised approach to determining beneficiary assignment and the revised definition of assignable beneficiary in establishing, adjusting, updating, and resetting historical benchmarks for ACOs entering new agreement periods beginning on January 1, 2025, and subsequent years. Also consistent with how we have implemented previous changes to the assignment methodology, we would adjust benchmarks for all ACOs in agreement periods for which performance year 2025 is a second or subsequent performance year at the start of performance year 2025, so that the ACO benchmarks reflect the use of the same assignment rules and definition of assignable beneficiary as would apply in the performance year (refer to §§ 425.601(a)(9) and 425.652(a)(9)). We believe that the expanded window for assignment and proposed step three represent a valuable change that would fill an important gap in the current assignment methodology. CMS has outlined a renewed vision and strategy for driving health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries.[159] In a January 2022 article, CMS stated our goal that 100 percent of people with Original Medicare will be in a care relationship with accountability for quality and total cost of care by 2030.[160] Many Medicare FFS beneficiaries are currently excluded from the assignable and Shared Savings Program assigned populations despite receiving primary care from ACO professional nurse practitioners, physician assistants, and clinical nurse specialists during the existing 12-month assignment window, and these excluded beneficiaries tend to come from populations characterized by greater social risk factors. Specifically, beneficiaries likely to be added to the assignable population are more likely to be disabled, be enrolled in the Medicare Part D LIS, and reside in areas with higher ADI scores (as described in section III.G.3.a.(2)(d) of this proposed rule). The proposed change to the assignment methodology represents an opportunity to not only grow the share of Medicare beneficiaries involved in accountable care relationships but to also support efforts to improve health equity in the Medicare program.

In summary, we seek comment on the proposed changes to establish a new defined term in § 425.20, expanded window for assignment, for use in a proposed additional step three in the beneficiary assignment methodology and in identifying the assignable beneficiary population, revisions to the definition of assignable beneficiary, as well as proposed technical and conforming changes to provisions of the Shared Savings Program regulations, including the definition of assignment window under § 425.20, and provisions within subpart E and subpart G. If finalized, the proposed changes would be applicable for the performance year beginning on January 1, 2025, and subsequent performance years. We welcome comments on any aspects of the proposed changes, including the length of the expanded window for assignment. We also seek comment on additional policies that CMS should consider for potential future rulemaking on our assignment methodology, with the goal of increasing the number of Original Medicare fee-for-service beneficiaries assigned to an ACO, particularly in underserved communities.

b. Proposed Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87

[159] See, for example, CMS Innovation Center ''Strategic Direction'' web page, at *https://innovation.cms.gov/strategic-direction.* See also, CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper.*

[160] Seshamani M, Fowler E, Brooks-LaSure C. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444.*

FR 69821 through 69825) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

For the performance year beginning on January 1, 2023, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(vii) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

- *CPT codes:*

++ 96160 and 96161 (codes for administration of health risk assessment).

++ 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

++ 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

++ 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

++ 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

++ 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

++ 99421, 99422, and 99423 (codes for online digital evaluation and management).

++ 99424, 99425, 99426, and 99427 (codes for principal care management services).

++ 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

++ 99439 (code for non-complex chronic care management).

++ 99483 (code for assessment of and care planning for patients with cognitive impairment).

++ 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

++ 99495 and 99496 (codes for transitional care management services).

++ 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

- *HCPCS codes:*

++ G0402 (code for the Welcome to Medicare visit).

++ G0438 and G0439 (codes for the annual wellness visits).

++ G0442 (code for alcohol misuse screening service).

++ G0443 (code for alcohol misuse counseling service).

++ G0444 (code for annual depression screening service).

++ G0463 (code for services furnished in ETA hospitals).

++ G0506 (code for chronic care management).

++ G2010 (code for the remote evaluation of patient video/images).

++ G2012 and G2252 (codes for virtual check-in).

++ G2058 (code for non-complex chronic care management).

++ G2064 and G2065 (codes for principal care management services).

++ G0317, G0318, and G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

++ G2214 (code for psychiatric collaborative care model).

++ G3002 and G3003 (codes for chronic pain management).

- Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of § 425.400 or a HCPCS code specified in paragraph (c)(1)(vi)(B) of § 425.400, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that we are proposing to recognize for payment starting in CY 2024, we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and to make other technical changes to the definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years, in order to remain consistent with billing and coding under the PFS.

We propose to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions: (1) Smoking and Tobacco-use Cessation Counseling Services CPT codes 99406 and 99407; (2) Remote Physiologic Monitoring CPT codes 99457 and 99458; (3) Cervical or Vaginal Cancer Screening HCPCS code G0101; (4) Office-Based Opioid Use Disorder Services HCPCS codes G2086, G2087, and G2088; (5) Complex Evaluation and Management Services Add-on HCPCS code G2211, if finalized under Medicare FFS payment policy; (6) Community Health Integration services HCPCS codes GXXX1 and GXXX2, if finalized under Medicare FFS payment policy; (7) Principal Illness Navigation (PIN) services HCPCS codes GXXX3 and GXXX4, if finalized under Medicare FFS payment policy; (8) SDOH Risk Assessment HCPCS code GXXX5, if finalized under Medicare FFS payment policy; (9) Caregiver Behavior Management Training CPT Codes 96202 and 96203, if finalized under Medicare FFS payment policy; and (10) Caregiver Training Services CPT codes 9X015, 9X016, and 9X017, if finalized under Medicare FFS payment policy. The following provides additional information about the HCPCS codes that we are proposing to add to the definition of primary care services used for purposes of beneficiary assignment:

- *Smoking and tobacco-use cessation counseling services CPT codes 99406 and 99407:* Effective January 1, 2008, CPT codes 99406 (*Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes*) and 99407 (*Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes*) were implemented for billing for smoking and tobacco-use cessation counseling services. As described in Medicare National Coverage Determinations (NCD) Manual, Publication 100–3, chapter 1, section 210.4.1, tobacco use remains the leading cause of preventable morbidity and mortality in the U.S. and is a major contributor to the nation's increasing medical costs. Despite the growing list of adverse health effects associated with smoking, more than 45 million U.S. adults continue to smoke and approximately 1,200 die prematurely each day from tobacco-related diseases. Since these are recognized as preventive services,[161] similar to other preventive services such as alcohol misuse screening and counseling (HCPCS codes G0442 and G0443) which are currently included in the definition of primary care services for purposes of beneficiary assignment, we believe it appropriate to include CPT codes that identify counseling to prevent tobacco use in the definition of

[161] Medicare Learning Network (MLN006559, May 2023) Medicare Preventive Services Quick Reference Chart, available at: *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#TOBACCO.*

primary care services for purposes of beneficiary assignment.

• *Remote Physiologic Monitoring CPT codes 99457 and 99458:* Chronic care remote physiologic monitoring (RPM) services involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan. In the CY 2020 PFS final rule (84 FR 62697) we finalized a revised CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; initial 20 minutes*) and added CPT code 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes*) to adopt the CPT Editorial Panel revised structure for CPT code 99457. The new code structure retained CPT code 99457 as a base code that describes the first 20 minutes of the treatment management services, and uses a new add-on code to describe subsequent 20-minute intervals of the service. We further designated CPT codes 99457 and 99458 as care management services because care management services include establishing, implementing, revising, or monitoring treatment plans, as well as providing support services, and because RPM services include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely. Because these remote therapeutic monitoring services are designated as care *management* services [162] and because we broadly include care management services (for example, CPT codes 99437, 99487, 99489, 99490 and 99491) in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we believe CPT codes 99457 and 99458 should also be included in the definition of primary care services for purposes of beneficiary assignment.

• *Cervical or Vaginal Cancer Screening Code HCPCS code G0101:* Section 4102 of the Balanced Budget Act of 1997 provides for coverage of screening pelvic examinations (including a clinical breast examination) for all female beneficiaries, subject to certain frequency and other limitations.[163] Cervical and vaginal cancer screening and clinical breast examination are important preventive health care services intended to detect early cancer, precancers and sexually transmitted infections. HCPCS code G0101 (*Cervical or vaginal cancer screening; pelvic and clinical breast examination*) can be reimbursed by Medicare Part B every 2 years. For patients who are considered high risk, it is allowed on an annual basis. Obstetrics/gynecology and gynecology/oncology are identified as physician specialty designations for purposes of identifying primary care services furnished to beneficiaries used in assignment operations according to § 425.402(c), so we believe it appropriate to use wellness and preventive care visits provided by these specialists in our definition of primary care services used in assignment. CMS considers these to be a preventive health service that can be provided in a primary care setting [164] similar to the annual wellness visit HCPCS codes G0438 and G0439, which are already included in the Shared Savings Program definition of primary care services used in assignment, so we believe that they should be included in the definition of primary care services for purposes of beneficiary assignment.

• *Office-Based Opioid Use Disorder Services HCPCS Codes G2086, G2087, and G2088:* In the CY 2020 PFS final rule (84 FR 62568) we finalized our proposal to establish bundled payments for the overall treatment of Opioid Use Disorder (OUD), including management, care coordination, psychotherapy, and counseling activities HCPCS codes G2086 (*Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month*), G2087 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month*), and G2088 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure)*). Refer to the CY 2020 PFS final rule (84 FR 62673) for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

The bundled payment under the PFS for office-based treatment for OUD was intended to create an avenue for physicians and other health professionals to bill for a bundle of services that is similar to the bundled OUD treatment services benefit, but not furnished by an Opioid Treatment Program (OTP). By creating a separate bundled payment for these services under the PFS, we hoped to incentivize increased provision of counseling and care coordination for patients with OUD in the office setting, thereby expanding access to OUD care. We note that use of these codes is limited to only beneficiaries diagnosed with OUD and these codes should not be billed for beneficiaries who are receiving treatment at an OTP, as we believe that would be duplicative since the bundled payments made to OTPs cover similar services for the treatment of OUD.

Because the separately reportable initiating visit requirement for the OUD bundle HCPCS codes G2086, G2087 and G2088 is similar to the separately reportable initiating visit requirements for chronic care management (CCM) services, and behavioral health integration services (BHI), as they include overall management and care coordination activities, we believe these services should be considered primary care services for purposes of beneficiary assignment.[165] Additionally, we anticipate that the billing clinician, likely an addiction medicine specialist, would manage the patient's overall OUD care, as well as supervise any other individuals participating in the treatment, such as those billing incident to services of the billing physician or other practitioner, which is similar to the requirements related to the furnishing of psychiatric collaborative care model (CoCM) services. CCM, BHI,

[162] Medicare Physician Fee Schedule Care Management Services Information, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.*

[163] Medicare National Coverage Determination for Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancers (Pub. No. 100–3, Manual Section 210.2), available at: *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=185#:~:text=Section%204102%20of%20the%20Balanced%20Budget%20Act%20of,beneficiaries%2C%20subject%20to%20certain%20frequency%20and%20other%20limitations.*

[164] Medicare Learning Network (MLN006559, May 2023) Medicare Preventive Services Quick Reference Chart, available at: *https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#PELVIC.*

[165] Medicare Physician Fee Schedule Office-Based Opioid Use Disorder (OUD) Treatment Billing Information, available at: *https://www.cms.gov/medicare/physician-fee-schedule/office-based-opioid-use-disorder-oud-treatment-billing.*

CoCM, and alcohol misuse screening and counseling services are included in our definition of primary care services, so we believe that HCPCS codes G2086, G2087 and G2088 are appropriate to be included in the definition of primary care services for purposes of beneficiary assignment. For additional clarity, incident to services are services rendered to a patient by a provider other than the physician treating the patient more broadly, that are an integral, although incidental, part of the patient's normal course of diagnosis or treatment of an injury or illness. These services are billed as Medicare Part B services, as if the original physician personally provided the care using that physician's NPI number. We anticipate that these services would often be billed by addiction specialty practitioners but note that these codes are not limited to use by any particular physician or non-physician practitioner specialty. Further, since addiction medicine is identified as one of the physician specialty designations for purposes of identifying primary care services used in assignment operations according to § 425.402(c)(13), we believe it would be appropriate to include care coordination services provided by these specialists in our definition of primary care services used for purposes of beneficiary assignment.

We further recognize that OUD bundle HCPCS codes G2086, G2087 and G2088 are identified as codes for alcohol and substance abuse-related diagnoses that are excluded from Shared Savings Program Claim and Claim Line Feeds. Given this, we want to make transparent that ACOs will not be able to see the claims that may have been used in assignment for beneficiaries receiving OUD services, and possibly not be able to identify why certain beneficiaries were assigned to their ACO related to these codes.

• *Complex Evaluation and Management Services Add-on HCPCS Code G2211, if finalized under Medicare FFS payment policy:* As discussed in section II.F. of this proposed rule, HCPCS add-on code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*) can be reported in conjunction with office/outpatient (O/O) evaluation and management (E/M) visits to better account for additional resources associated with primary care, or similarly ongoing medical care related to a patient's single, serious condition, or complex condition (84 FR 62854 through 62856, 85 FR 84571). Section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) imposed a moratorium on Medicare payment for this service by prohibiting CMS from making payment under the PFS for inherently complex E/M visits described by HCPCS code G2211 (or any successor or substantially similar code) before January 1, 2024. The moratorium on Medicare payment under the PFS for HCPCS code G2211 will end on December 31, 2023, therefore we are proposing to make HCPCS code G2211 separately payable effective January 1, 2024. Refer to section II.F. of this proposed rule for detailed, technical discussion regarding the description, payment, and utilization of these HCPCS codes.

Since G2211 is an add on code used in conjunction with O/O E/M services and such services are included in our definition of primary care services, we believe that the proposed inclusion of HCPCS code G2211 is consistent with our intent to encompass primary care and wellness services in the definition of primary care services used for purposes of beneficiary assignment.

• *Community Health Integration Services HCPCS Codes GXXX1 and GXXX2, if finalized under Medicare FFS payment policies:* In section II.E. of this proposed rule, separate coding, payment, service elements and documentation requirements for the following Community Health Integration (CHI) services are being proposed:

GXXX1—Community health integration (CHI) services performed by certified or trained auxiliary personnel including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

• *Person-centered assessment, performed to better understand the individualized context of* the *intersection between* the *SDOH need(s) and problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal-setting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

• *Practitioner, Home, and Community-Based Care Coordination:*

++ *Coordination with practitioner; home, and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and* needs, *functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address SDOH need(s).*

• *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis and treatment.*

• *Health care access/health system navigation:*

++ *Helping the patient access care, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

• *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

• *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines*

to better meet diagnosis and treatment goals.

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

As proposed in section II.E. of this proposed rule, all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements and authorized to perform them under applicable State laws and regulations. Under § 410.26(a)(1) of our regulations, auxiliary personnel must meet any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.[166] A billing practitioner may arrange to have CHI services provided by auxiliary personnel external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of CHI services are met. The payment policy proposal explains that we would expect the auxiliary personnel performing the CHI services to communicate regularly with the billing practitioner to ensure that CHI services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for CHI services to address the SDOH need(s) that limit the practitioner's ability to diagnose and treat the problem(s) addressed in the initiating visit. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the proposed description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes to designate CHI services as care management services that may be furnished under general supervision under § 410.26(b)(5) and because we broadly include care management services in the definition of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include CHI services in the list of primary care services used for purposes of beneficiary assignment. Additionally, since CHI services require an initiating E/M visit and these services can be billed as incident to by the billing practitioner who bills for the CHI initiating E/M visit, and E/M services are currently included in the list of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include CHI services in the list of primary care services used for purposes of beneficiary assignment.

• *Principal Illness Navigation (PIN) Services HCPCS codes GXXX3 and GXXX4, if finalized under Medicare FFS payment policies:* In section II.E. of this proposed rule, new coding for Principal Illness Navigation (PIN) services is being proposed. In considering the appropriate patient population to receive these services, we considered the patient population eligible for principal care management service codes (CPT codes 99424 through 99427), as well as clinical definitions of ''serious illness.'' For example, one peer-review study defined ''serious illness'' as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers.[167] Another study describes a serious illness as a health condition that carries a high risk of mortality and commonly affects a patient for several years, while some measure serious illness by the amount of urgent health care use (911 calls, emergency department visits, repeated hospitalizations) and polypharmacy.[168] The navigation services such patients need are similar to CHI services, but Social Determinants of Health (SDOH) need(s) may be fewer or not present. Accordingly, a parallel set of services focused on patients with a serious, high-risk illness who may not necessarily have SDOH-related needs is being proposed. PIN services could be furnished following an initiating E/M visit addressing a single high-risk disease.

The following codes would be reported for PIN services:

GXXX3—Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

• *Person-centered assessment, performed to better understand the individualized context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal setting and creating an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

• *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*

• Practitioner, Home, and Community-Based Care Coordination

++ *Coordinating receipt of needed services from healthcare practitioners, providers and facilities; home-, and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, and preferences, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referrals to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).*

• *Health education—Helping the patients contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver, if applicable) on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*

• *Health care access/health system navigation.*

++ *Helping the patient access healthcare, identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

• *Facilitating behavioral change necessary for meeting diagnosis and*

[166] CHW Roles As Outlined In The C3 Project available at: *https://chwtraining.org/c3-project-chw-skills/.*

[167] Kelley AS, Bollens-Lund E. Identifying the Population with Serious Illness: The ''Denominator'' Challenge. J Palliat Med. 2018 Mar;21(S2):S7–S16. doi: 10.1089/jpm.2017.0548. Epub 2017 Nov 10. PMID: 29125784; PMCID: PMC5756466. available at *https://pubmed.ncbi.nlm.nih.gov/29125784/.*

[168] Silver, Alison. Serious Illness: A High Priority for Accountable Care. The American Journal of Accountable Care. 2020;8(2):32–33. available at *https://www.ajmc.com/view/serious-illness-a-high-priority-for-accountable-care.*

treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.

- *Facilitating and providing social and emotional support for the patient to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis or treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

As discussed in section II.E. of this proposed rule, a billing practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the ''incident to'' and other requirements and conditions for payment of PIN services are met. We would expect the auxiliary personnel performing the PIN services to communicate regularly with the billing practitioner to ensure that PIN services are appropriately documented in the medical record, and to continue to involve the billing practitioner in evaluating the continuing need for PIN services to address the serious, high-risk condition. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes to designate PIN services as care management services that may be furnished under general supervision under § 410.26(b)(5) and because we broadly include care management services in the list of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include PIN services in the list of primary care services used for purposes of beneficiary assignment. Additionally, since these services are meant to provide assistance to the beneficiary through communication and coordination with practitioners, providers, including referrals to other clinicians and follow-up after emergency or inpatient care, we believe that these services can further the ACO's goal of care coordination and the provision of value-based care and should, therefore, be included in the definition of primary care services for purposes of beneficiary assignment. Further, since PIN services require an initiating E/M visit and these services can be billed as incident to by the billing practitioner who bills for the PIN initiating E/M visit, and E/M services are currently included in the list of primary care services used for purposes of beneficiary assignment, we believe it would be similarly appropriate to include PIN services in the list of primary care services used for purposes of beneficiary assignment.

- *SDOH Risk Assessment HCPCS code GXXX5, if finalized under Medicare FFS payment policies:* In section II.E. of this proposed rule, a new stand-alone G code, GXXX5 (*administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5–15 minutes, at most every 6 months.*) is being proposed to identify and value the work involved in the utilization of SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. SDOH risk assessment through a standardized, evidence-based tool can more effectively and consistently identify unmet SDOH needs and enables comparisons across populations. The SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's treatment plan that is established during the visit. Required elements are described in detail in the payment policy proposal described in section II.E.

Under the proposal described in section II.E. of this proposed rule, the practitioner billing or furnishing the SDOH risk assessment would be required to have the ability to furnish CHI or other care management services. Given the multifaceted nature of SDOH needs, ensuring adequate referral to appropriate services and supports is critical for addressing both the SDOH need and the impact of that need on the patient's health. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Additionally, the proposal detailed in section III.T of this proposed rule proposes to add elements to the Annual Wellness Visit (AWV) by adding a new SDOH Risk Assessment as an optional, additional element with an additional payment. Under this proposal, the SDOH Risk Assessment would be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV, and would inform the care the patient is receiving during the visit, including taking a medical and social history, applying health assessments, and conducting prevention services education and planning.

Since the proposals described in sections II.E. and III.T. of this proposed rule propose that these services would be provided in conjunction with professional services, such as E/M visits, which can be provided in a primary care setting, we believe it would be appropriate to include these services in the definition of primary care services for purposes of beneficiary assignment. Additionally, since these are separately payable services when provided with an AWV and the AWV is included in the Shared Savings Program definition of primary care services for purposes of beneficiary assignment, we believe it would be appropriate to include SDOH risk assessment in the definition of primary care services for purposes of beneficiary assignment. Further, since these services precede the utilization of CHI, PIN, and Care Management services, which are either currently included or proposed to be included in the definition of primary care services for purposes of assignment, we believe the inclusion of the new SDOH risk assessment HCPCS code would be appropriate as well.

- *Caregiver Behavior Management Training CPT Codes 96202 and 96203, if finalized under Medicare FFS payment policy:* CPT code 96202 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; initial 60 minutes*) and its add-on code, CPT code 96203 (*Multiple-family group behavior management/modification training for guardians/caregivers of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers; each additional 15 minutes (List separately in addition to code for primary service)*) are two new codes created by the CPT Editorial Panel during its February 2021 meeting used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing group training to guardians or caregivers of patients. Although the patient does not attend the group trainings, the goals and outcomes of the

sessions focus on interventions aimed at improving the patient's daily life.

In section II.E. of this proposed rule, an active payment status for CPT codes 96202 and 96203 (caregiver behavior management/modification training services) is being proposed for CY 2024. These codes allow treating practitioners to report training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. Caregiver behavior management/modification training services may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The caregiver behavior management/modification training services themselves need to be congruent with the treatment plan in order to effectuate the desired patient outcomes.

For purposes of caregiver behavior management/modification training services, the proposal requires that a caregiver receiving behavior management/modification training services is a family member, friend, or neighbor who provides unpaid assistance to the patient, assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling). In this context, caregivers would be trained by the treating practitioner in strategies and specific activities that improve symptoms, functioning, adherence to treatment, and/or general welfare related to the patient's primary clinical diagnoses. Under this proposal, caregiver behavior management/modification training services may be furnished directly by the treating practitioner or provided by auxiliary personnel incident to the treating practitioner's professional services as specified in 42 CFR 410.26, as applicable for the types of practitioners whose covered services include ''incident to'' services. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes that these services can be billed as incident to by the billing practitioner who could be a primary care physician who also bills for an E/M visit, and these services cannot duplicate services provided in conjunction with transitional care management, chronic care management, behavioral health integration services, and virtual check-in services which are currently included in the list of primary care services used for purposes of beneficiary assignment, we believe that these services should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings mission to give coordinated, high quality care to an ACO's Medicare beneficiaries.

• *Caregiver Training Services CPT codes 9X015, 9X016, and 9X017, if finalized under Medicare FFS payment policy:* CPT codes 9X015 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes*), add-on code, CPT code 9X016 (*each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015)*), and 9X017 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers*) are new codes created by the CPT Editorial Panel during its October 2022 meeting. The three codes are to be used to report the total duration of face-to-face time spent by the physician or other qualified health professional providing individual or group training to caregivers of patients. Although the patient does not attend the trainings, the goals and outcomes of the sessions focus on interventions aimed at improving the patient's ability to successfully perform activities of daily living (ADLs). Activities of daily living generally include ambulating, feeding, dressing, personal hygiene, continence, and toileting.

These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. As discussed above, we believe training furnished to a caregiver may be reasonable and necessary when it is integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. The Caregiver Training Services (CTS) themselves need to be congruent with the treatment plan in order to effectuate the desired patient outcomes, especially in medical treatment scenarios where the caregiver receiving CTS is necessary to ensure a successful treatment outcome for the patient.

In section II.E., an active payment status for CPT codes 9X015, 9X016, and 9X017 for CY 2024 under the PFS is proposed. CTS may be furnished directly by the treating practitioner or provided by auxiliary personnel incident to the treating practitioner's professional services as specified in 42 CFR 410.26, as applicable for the types of practitioners whose covered services include ''incident to'' services. Under this proposal, 9X015, 9X016, and 9X017 are designated as ''sometimes therapy''. This means that the services represented by these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care (that is, where the services are not integral to a therapy plan of care), they can be furnished under a treatment plan by physicians and NPPs. Refer to section II.E. of this proposed rule for detailed, technical discussion regarding the description, payment and utilization of these HCPCS codes.

Since the proposal described in section II.E. of this proposed rule proposes that these services can be billed as incident to by the billing practitioner who could be a primary care physician who also bills for an E/M visit, and these services cannot duplicate services provided in conjunction with transitional care management, chronic care management, behavioral health integration services, and virtual check-in services which are currently included in the list of primary care services used for purposes of beneficiary assignment, and we believe that these services are reported to Medicare only when furnished in conjunction with treatment for particular conditions and reflected in a plan of care, we believe they should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program mission to give coordinated, high quality care to an ACO's Medicare beneficiaries.

We propose to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(viii) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(vii) along with the proposed additional CPT codes 99406 and 99407, and 99457 and 99458, 96202 and 96203, if finalized under Medicare FFS payment policy; and 9X015, 9X016,

and 9X017, if finalized under Medicare FFS payment policy and HCPCS codes G0101; G2086, G2087, and G2088; G2211, if finalized under Medicare FFS payment policy; GXXX1 and GXXX2, if finalized under Medicare FFS payment policy; GXXX3 and GXXX4, if finalized under Medicare FFS payment policy; and GXXX5, if finalized under Medicare FFS payment policy; as discussed in the preceding paragraphs. We propose that the new provision at § 425.400(c)(1)(viii) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2024, and subsequent performance years.

We seek comment on these proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2024, and subsequent performance years. We also welcome comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed elsewhere in this proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

4. Benchmarking Methodology

a. Overview

In this section of the proposed rule, we are proposing modifications to the benchmarking methodology under the Shared Savings Program. We propose a combination of modifications to the Shared Savings Program's benchmarking methodology to encourage sustained participation by ACOs in the program. Specifically, we are proposing to revise the benchmarking methodology by modifying the existing calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year (section III.G.4.b. of this proposed rule). We are additionally proposing to further mitigate the impact of the negative regional adjustment to the historical benchmark (section III.G.4.c. of this proposed rule). We are also proposing refinements to the prior savings adjustment calculation methodology (section III.G.4.d. of this proposed rule), that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or a change in the amount of savings or losses for a benchmark year as a result of issuance of revised initial determination under § 425.315. Finally, we propose to specify in the regulations an approach to calculating prospective HCC risk scores used in Shared Savings Program benchmark calculations, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, in which we would use the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period (section III.G.4.e. of this proposed rule). Our specific proposals are discussed in detail in the following sections.

b. Proposal To Cap Regional Service Area Risk Score Growth for Symmetry With ACO Risk Score Cap

(1) Background

In the June 2016 final rule (81 FR 37977 through 37981), we established a policy of utilizing a regional growth rate to update the benchmark annually. In that rule, we finalized a policy that, for ACOs in their second or subsequent agreement period whose rebased historical benchmark incorporates an adjustment to reflect regional expenditures, the annual update to the benchmark would be calculated as a growth rate that reflects growth in risk adjusted regional per beneficiary FFS spending for the ACO's regional service area, for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible (refer to § 425.603(d)).

In proposing and finalizing the regional growth rate policy, we explained that incorporating regional expenditures in the benchmark would make the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region. We also explained that the use of regional trend factors to trend forward BY1 and BY2 to BY3 in resetting ACO benchmarks and regional growth rates used to update the historical benchmark to the performance year annually would likely result in relatively higher benchmarks for ACOs that are low growth relative to their region compared to benchmarks for ACOs that are high growth relative to their region (refer to 81 FR 37955).

In the December 2018 final rule (83 FR 68013 through 68031), we finalized a proposal to use a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark and a blend of national and regional update factors to update the historical benchmark to the performance year for all agreement periods beginning on or after July 1, 2019 (refer to § 425.601(a) and (b)). Under this policy, the national component of the blended trend and update factors receives a weight equal to the share of assignable beneficiaries in the regional service area that are assigned to the ACO, computed by taking a weighted average of county-level shares. The regional component of the blended trend and update factors receives a weight equal to 1 minus the national weight. Calculations are made separately for each Medicare enrollment type. In the December 2018 final rule (83 FR 68024), we acknowledged that, for an ACO that serves a high proportion of beneficiaries in select counties making up its regional service area (referred to herein as having ''high market share''), a purely regional trend would be more influenced by the ACO's own expenditure patterns, making it more difficult for the ACO to outperform its benchmark and conflicting with our goal to move ACOs away from benchmarks based solely on their own historical costs. Incorporating national trends that are more independent of an ACO's own performance was therefore intended to reduce the influence of the ACO's assigned beneficiaries on the ultimate blended trend and update factors applied.

In the CY 2023 PFS final rule (87 FR 69881 through 69899), we finalized a policy for agreement periods starting on or after January 1, 2024, under which we will update the historical benchmark between BY3 and the performance year for each year of the agreement period using a three-way blend calculated as a weighted average of a two-way blend of national and regional growth rates determined after the end of each performance year and a fixed projected growth rate determined at the beginning of the ACO's agreement period called the Accountable Care Prospective Trend (ACPT) (refer to § 425.652(b)). Under this policy, we will make separate calculations for expenditure categories for each Medicare enrollment type. We explained that incorporating this prospective trend in the update to the benchmark would insulate a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor.

For ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, we account for changes in severity and case mix of the ACO's assigned beneficiary population when establishing the benchmark for an agreement period and also in adjusting the benchmark for each performance year during the agreement period. In accordance with § 425.601(a)(3) and § 425.652(a)(3), in establishing the benchmark, we adjust expenditures for changes in severity and case mix using CMS Hierarchical Condition Category (CMS–HCC) prospective risk scores (herein referred to as prospective HCC risk scores). Pursuant to § 425.601(a)(10) and § 425.652(a)(10), we further adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year (refer to § 425.605(a)(1), (a)(2); § 425.610(a)(2), (a)(3)). In performing this risk adjustment, we make separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

As finalized in the CY 2023 PFS final rule (87 FR 69932 through 69946), for agreement periods beginning on or after January 1, 2024, we will use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, with positive adjustments subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points (herein referred to as the ''aggregate demographics plus 3 percent cap'') (refer to § 425.605(a)(1)(ii); § 425.610(a)(2)(ii)). This cap applies only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) exceeds this cap. If the cap is determined to apply, the value of the cap is the maximum increase in prospective HCC risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for the applicable performance year, such that any positive adjustment between BY3 and the performance year cannot be larger than the value of the aggregate demographics plus 3 percent cap for any of the Medicare enrollment types. This cap is applied separately for the population of beneficiaries in each Medicare enrollment type.

In the CY 2023 PFS final rule, we further explained that we were finalizing the aggregate demographics plus 3 percent cap to address concerns with the prior approach to risk adjustment, which used prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, subject to a cap of positive 3 percent for the agreement period that was applied separately by Medicare enrollment type (referred to herein as the ''3 percent cap'') (refer to § 425.605(a)(1)(i); § 425.610(a)(2)(i)). The 3 percent cap was finalized through the December 2018 final rule (83 FR 68013) and is applicable to ACOs in agreement periods beginning on or after July 1, 2019, and prior to January 1, 2024.

We believe that the aggregate demographics plus 3 percent cap addresses several concerns raised by interested parties [169] about the 3 percent cap by: accounting for higher volatility in prospective HCC risk scores for certain Medicare enrollment types due to smaller sample sizes; allowing for higher benchmarks than the prior risk adjustment methodology for ACOs that care for larger proportions of beneficiaries in aged/dual eligible, disabled and ESRD enrollment types (which are frequently subject to the 3 percent cap); and continuing to safeguard the Trust Funds by limiting returns from coding initiatives. However, the demographics plus 3 percent cap does not address concerns from certain interested parties that the current policy places a cap on an ACO's risk score growth between BY3 and the performance year but does not place a cap on the regional prospective HCC risk score growth between BY3 and the performance year, which is reflected in the regional growth rate used to calculate the update factor (pursuant to § 425.652(b)(2)(ii)).[170]

Under the methodology finalized in CY 2023 PFS final rule, as described in § 425.652(b), we express the regional update factor, used to update the historical benchmark to the performance year, as the ratio of an ACO's performance year regional service area risk adjusted expenditures to its BY3 regional service area risk adjusted expenditures for each Medicare enrollment type. Table 31 provides a numeric example of the current methodology for calculating the regional update factor for the ESRD Medicare enrollment type for a hypothetical ACO with a regional service area that includes counties A, B, C, and D.

Pursuant to § 425.654, an ACO's regional expenditures are calculated using risk adjusted county FFS expenditures. The counties included in the ACO's regional service area are based on the ACO's assigned beneficiary population for the applicable benchmark or performance year. We determine average county FFS expenditures based on expenditures for the assignable population [171] of beneficiaries in each county in the ACO's regional service area. We make separate calculations for each Medicare enrollment type. We adjust these county-level FFS expenditures (refer to Table 31, rows [A] and [F]) for severity and case mix of assignable beneficiaries in the county using county-level prospective HCC risk scores (refer to Table 31, rows [B] and [G]). The adjustment is made by dividing the county-level FFS expenditures for the Medicare enrollment type by county-level prospective HCC risk scores for the Medicare enrollment type, resulting in risk adjusted county-level FFS expenditures shown in Table 31 rows [C] and [H].

We then calculate an ACO's regional expenditures for each Medicare enrollment type by weighting these risk adjusted county-level FFS expenditures according to the ACO's proportion of assigned beneficiaries [172] in the county for that Medicare enrollment type (refer to Table 31, rows [D] and [I]), determined by the number of the ACO's

[169] For summaries of these concerns of interested parties, refer to the CY 2022 PFS final rule (86 FR 65302 through 65306), CY 2023 PFS final rule (87 FR 69932 *through* 69934).

[170] For summaries of these concerns of interested parties, refer to the CY 2021 PFS final rule (85 FR 84783 through 84785), the CY 2022 PFS final rule (86 FR 65302 through 65306), and the CY 2023 PFS final rule (87 FR 66942 and 69943).

[171] Assignable beneficiary expenditures are calculated using the payment amounts included in Parts A and B FFS claims with dates of service in the 12-month calendar year that corresponds to the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. These expenditure calculations exclude IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals; and consider individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. Refer to § 425.654(a)(2). The assignable population of beneficiaries is identified for the assignment window corresponding to the relevant benchmark or performance year that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii). Refer to § 425.654(a)(1)(i). We refer readers to the discussion of the proposed changes to the methodology for identifying the assignable beneficiary population in section III.G.3.a of this proposed rule.

[172] Proportions are calculated using beneficiary person years.

assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year. We then aggregate those values for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area [173] (refer to Table 31, rows [E] and [J]).

We then calculate the regional update factor as the ratio of an ACO's performance year expenditures to BY3 regional expenditures. This calculation is performed separately for each Medicare enrollment type. Refer to Table 31, row [K] for an example of how the regional update factor would be calculated for the ESRD Medicare enrollment type. This calculation would then be repeated for each of the other Medicare enrollment types.

TABLE 31: Example Calculation of the Regional Update Factor for the ESRD Medicare Enrollment Type for a Hypothetical ACO

	County A	County B	County C	County D	Regional
BY3 ESRD Calculations					
[A] County FFS Expenditures	72,000	108,000	86,400	79,200	
[B] County Prospective HCC Risk Scores	0.980	1.100	1.050	1.100	
[C] Risk Adjusted County FFS Expenditures, [A]/[B]	73,469	98,182	82,286	72,000	
[D] Proportion of Assigned Beneficiaries	0.55	0.30	0.15	0.00	
[E] Regional Risk Adjusted Expenditures, weighted average of [C] using weights [D]					**82,206**
PY ESRD Calculations					
[F] County FFS Expenditures	74,880	112,320	89,856	82,368	
[G] County Prospective HCC Risk Scores	1.000	1.210	1.124	1.166	
[H] Risk Adjusted County FFS Expenditures, [F]/[G]	74,880	92,826	79,943	70,642	
[I] Proportion of Assigned Beneficiaries	0.58	0.26	0.15	0.01	
[J] Regional Risk Adjusted Expenditures, weighted average of [H] using weights [I]					**80,263**
ESRD Regional Update Factor Calculation					
[K] ESRD Regional Update Factor, [J]/[E]					**0.976**

While the regional expenditures for BY3 and the performance year are risk adjusted, as described previously in this section, there is currently no cap on prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year. As discussed previously in this section, ACOs and other interested parties have expressed concerns that the program's current cap on ACO risk score growth between BY3 and the performance year does not account for risk score growth in the ACO's regional service area and that there is not an equivalent cap on regional risk score growth. High prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year has the effect of decreasing the regional update factor, resulting in a lower updated benchmark for the ACO than if the regional risk score growth were capped (assuming that the risk score growth was high enough to be capped). In past rulemaking, some commenters have encouraged CMS to adopt a policy of applying a cap on ACO risk score growth after accounting for regional increase in risk scores.[174] Others have suggested more generally that CMS align the use of a risk adjustment cap for the ACO and its region by applying a consistent capping policy to both.[175]

In the CY 2022 PFS proposed rule (86 FR 39294 through 39295), we sought comment on an alternate approach to capping ACO prospective HCC risk score growth between BY3 and the performance year in relation to the prospective HCC risk score growth in the ACO's regional service area. The option we presented was to allow an ACO's risk score growth cap to increase above 3 percent by a percentage of the difference between the 3 percent cap and risk score growth in the AC''s regional service area for a given Medicare enrollment type. In this alternate approach (herein referred to as the ''3 percent cap plus regional difference''), the percentage applied would be equal to 1 minus the ACO's regional market share for the Medicare enrollment type. For example, if regional risk score growth for a particular Medicare enrollment type was 5 percent and the ACO's regional market share was 20 percent, we would increase the cap on the ACO's risk score growth for that Medicare enrollment type by an amount equal to the difference between the regional risk

[173] Refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), sections 4.1.1 ''Determining Regional FFS Expenditures'' and 4.1.4 ''Risk Adjusting and Updating the Historical Benchmark'', available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2.*

[174] Refer to CY 2021 PFS final rule (85 FR 84784).

[175] Refer to CY 2021 PFS final rule (85 FR 84784) and CY 2023 PFS final rule (87 FR 69943).

score growth and the 3 percent cap (2 percent) multiplied by one minus the ACO's regional market share (80 percent). Thus, the ACO would face a cap for this Medicare enrollment type equal to 4.6 percent instead of 3 percent (3 percent + (2 percent × 80 percent)). This approach would raise the 3 percent cap while limiting the ability for ACOs with high market share to increase their cap by engaging in coding intensity initiatives that raise the regional prospective HCC risk score. As discussed in the CY 2022 PFS final rule, a few commenters noted their support for this 3 percent cap plus regional difference methodology.[176] MedPAC, however, expressed concern that increasing the cap beyond 3 percent could effectively reward ACOs for greater coding intensity in their region, particularly for those with higher market share.[177] [178]

In the CY 2023 PFS final rule (87 FR 69932 through 69946), we indicated that we had considered the 3 percent cap plus regional difference methodology described in the CY 2022 PFS proposed rule. However, we opted not to propose this policy and instead proposed, and ultimately finalized, the aggregate demographics plus 3 percent cap. One reason we did not propose the 3 percent cap plus regional difference was that a relatively small share of ACOs affected by the 3 percent cap operated in regional service areas where regional risk score growth was greater than 3 percent, indicating that this was not a widespread issue impacting ACO performance. Additionally, we explained that we still had concerns that allowing the cap on an ACO's risk score growth to increase with regional risk score growth could incentivize ACOs, particularly those with high market share, to engage in coding behavior that would increase their cap, even if this incentive would be mitigated to some degree by limiting the allowable increase in the cap based on the ACO's market share. Under the 3 percent cap, ACOs with high market share have a disincentive to engage in coding initiatives, as it could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor. We noted that raising the 3 percent cap based on risk score growth in an ACO's regional service area could change these incentives and encourage ACOs to engage in coding initiatives. In addition to finalizing the aggregate demographics plus 3 percent cap, in the CY 2023 PFS final rule, we noted that we declined to consider an approach that would impose a direct cap on risk score growth in an ACO's regional service area (87 FR 69932 through 69947). As with the 3 percent cap plus regional difference, we were concerned that such an approach would create adverse incentives for coding behavior, especially for ACOs with high market share.

In response to the discussion of the cap on prospective HCC risk score growth in the CY 2023 PFS proposed rule, commenters took the opportunity to reiterate their concerns that the program's current cap on ACO risk score growth between BY3 and the performance year does not account for risk score growth in the ACO's regional service area and suggested ways to incorporate a cap on regional risk score growth. A couple of commenters requested that the risk score cap be allowed to further increase for ACOs in regions where risk score growth exceeds the cap, with one stating that a flat percentage cap will always disadvantage ACOs in regions where risk score growth exceeds the cap and another stating that this additional flexibility would ensure ACOs are not disadvantaged by operating in underserved communities. Additionally, many commenters supported capping regional risk score growth in addition to capping ACO risk score growth. Several of those commenters stated that it was critical that, whatever policy CMS adopted for capping ACOs' risk score growth, the same policy must also apply to regional risk score growth. Several commenters noted that CMS should not apply adjustments to only one side of the equation, that is, capping ACO risk ratios without capping regional risk ratios, with many commenters saying this would lead to unintended consequences and another commenter saying it would have inequitable results. Several commenters stated that not capping increases in regional risk scores would stifle growth in exactly the areas CMS wants growth the most. A few commenters explained that lack of regional risk score growth caps incentivizes ACOs not to grow in places with certain types of populations, such as those with increasing health burdens, higher needs, or higher numbers of aged/dual and disabled enrollees.[179] In response to these comments, we indicated that we would continue to monitor the impacts of regional risk score growth and may propose further refinements to our risk adjustment policies in future rulemaking.[180]

(2) Proposed Revisions

Since the publication of the CY 2023 PFS final rule, we have performed further analysis on prospective HCC risk score growth in ACOs' regional service area between BY3 and the performance year and considered ways in which we could reduce impacts to ACOs in regions with high risk score growth, particularly when such growth is not due to the ACO's own complete and accurate coding, while also limiting the impact from coding initiatives, particularly among ACOs with high market share. Based on this additional analysis, which is detailed later in this section, we are proposing to modify the calculation of the regional update factor used to update the historical benchmark between BY3 and the performance year. The proposed approach would cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor to the regional update factor. This cap on regional risk score growth would be applied independently of the cap on an ACO's own prospective HCC risk score growth between BY3 and the performance year, meaning that this proposed cap on prospective HCC risk score growth in an ACO's regional service area would be applied whether or not the ACO's prospective risk score growth was capped when updating the benchmark between BY3 and the performance year. Applying these caps independently would be more equitable to ACOs serving high risk patients in regions with high risk score growth, and avoid creating incentives for ACOs to avoid high risk and more medically complex patients. Adjusting the regional service area risk score growth cap based on the percentage of original Medicare fee-for-service beneficiaries the ACO serves in the region would help to mitigate the impact an ACO's own coding initiatives have on risk score growth in the ACO's regional service area, particularly when the ACO has a greater influence on its regional service area risk score growth rate.

To determine the cap on prospective HCC risk score growth in an ACO's regional service area we propose to follow a similar methodology as the one adopted in the CY 2023 PFS final

[176] Refer to 86 FR 65304.

[177] Refer to 86 FR 65303 through 65305.

[178] Refer to Letter from MedPAC to Chiquita Brooks-LaSure, Administrator, CMS (September 9, 2021), regarding File code CMS–1751–P (pages 16–18 ''Risk adjustment methodology''), available at *https://www.medpac.gov/wp-content/uploads/2021/10/09092021_PartB_CMS1751_MedPAC_Comment_V2_SEC.pdf*.

[179] Refer to 87 FR 69942 through 69943.

[180] Refer to 87 FR 69943.

rule [181] for capping ACO risk score growth, codified at § 425.605(a)(1)(ii) and § 425.610(a)(2)(ii), while additionally accounting for an ACO's aggregate market share. The effect of the regional risk score growth cap would be to increase the regional component of the update factor for ACOs in regions with aggregate regional prospective HCC risk score growth above the cap, with ACOs with higher aggregate market shares seeing smaller increases, all else being equal. ACOs in regions with aggregate regional prospective HCC risk score growth below the cap would not be affected by the proposed policy.

By symmetrically limiting risk score growth within both an ACO's assigned beneficiary population and its region, this proposed approach is expected to improve the accuracy of the regional update factors for ACOs operating in regional service areas with high risk score growth, particularly in later years of the 5-year agreement period where the difference between an ACO's BY3 and performance year regional risk scores is expected to be the greatest. We believe capping regional risk score growth will strengthen incentives for ACOs to form or continue to operate in regions with high risk score growth and thereby incentivize ACOs to care for higher risk beneficiaries. This approach would also offer an incentive for potential applicant ACOs that may be examining recent risk score growth in their region and making the decision whether to participate in the Shared Savings Program. Additionally, by adjusting the regional risk score growth cap based on ACO market share, this proposal would also maintain a disincentive against coding intensity for ACOs with high market share.

To implement the new cap on regional risk score growth, we would multiply the original regional update factor used to update the historical benchmark between BY3 and the performance year (determined in accordance with § 425.652(b)(2)(ii)) by a regional risk score growth cap adjustment factor. The regional risk score growth cap adjustment factor would be calculated as follows:

- *Step 1:* Calculate county-level risk scores. We would calculate county-level prospective HCC and demographic risk scores by Medicare enrollment type for both BY3 and the performance year. To do this for a given benchmark or performance year, we would first determine the renormalized, prospective HCC and demographic risk score for each assignable beneficiary [182] in each county in the ACO's regional service area. For both HCC and demographic risk scores, we would then compute the weighted average risk score for each county for each Medicare enrollment type by multiplying each assignable beneficiary's risk score for that Medicare enrollment type by the beneficiary's person years enrolled in that Medicare enrollment type, summing these weighted risk scores across all assignable beneficiaries for that Medicare enrollment type in the county, and then dividing by total person years for that Medicare enrollment type among assignable beneficiaries in the county. Note that this approach would be similar to the approach that is currently used to determine county-level prospective HCC risk scores as an intermediate step in calculating risk adjusted regional expenditures under the current methodology.[183]
- *Step 2:* Calculate regional risk scores. We would calculate regional-level BY3 and performance year prospective HCC and demographic risk scores as a weighted average of county-level HCC and demographic risk scores for the Medicare enrollment type (calculated in step 1), with weights reflecting the proportion of the ACO's assigned beneficiaries [184] in the county. This proportion is determined by the number of the ACO's assigned beneficiaries (by Medicare enrollment type) residing in each county in relation to the ACO's total number of assigned beneficiaries for that Medicare enrollment type for the relevant benchmark or performance year. These would be the same weights as used to calculate regional expenditures under § 425.654(b).
- *Step 3:* Determine aggregate growth in regional risk scores. To calculate aggregate growth in regional risk scores, we would first calculate growth in prospective HCC and demographic risk scores between BY3 and the performance year for each Medicare enrollment type, expressed as the ratio of the performance year regional risk score for a Medicare enrollment type (calculated in step 2) to the BY3 regional risk score for that enrollment type (calculated in step 2). We would next take a weighted average of the regional prospective HCC or demographic risk ratios, as applicable, across the four Medicare enrollment types, where the weight applied to the growth in risk scores for each Medicare enrollment type would be the ACO's performance year assigned beneficiary person years for the Medicare enrollment type multiplied by the ACO's regionally adjusted historical benchmark expenditures for the Medicare enrollment type.[185]
- *Step 4:* Determine the cap on regional risk score growth. We would first calculate the non-market share adjusted cap on the ACO's regional risk score growth as the sum of the aggregate growth in regional demographic risk scores (calculated in step 3) and 3 percentage points.[186]

We would next adjust the cap to reflect the ACO's aggregate market share. We would calculate an ACO's aggregate market share as a weighted average of the ACO's market share across the four Medicare enrollment types. An ACO's market share for each Medicare enrollment type would be equal to the weight that is applied to the national component of the blended update factor in the two-way blend that is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year (refer to § 425.652(b)(2)(iv)). The weights for each Medicare enrollment type used to compute the weighted average would be the ACO's performance year assigned person years for the Medicare enrollment type.

We would adjust the cap on regional risk score growth to reflect the ACO's aggregate market share by adding to the non-market share adjusted cap the product of:

++ The ACO's aggregate market share, and

++ The difference (subject to a floor of zero) between:

[181] 87 FR 69932 through 69946.

[182] Consistent with our proposal to revise the definition of an assignable beneficiary (refer to section III.G.3.a of this proposed rule), we propose that the assignable population of beneficiaries for a benchmark or performance year would be identified using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the applicable performance year according to § 425.400(a)(4)(ii).

[183] Refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), section 4.1.1 ''Determining Regional FFS Expenditures'', available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2*.

[184] Proportions are calculated using beneficiary person years.

[185] These are the same weights that are to be used when calculating weighted average ACO prospective HCC and demographic risk ratios under the risk adjustment methodology adopted in the CY 2023 PFS final rule (87 FR 69932 through 69946) and codified in §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C).

[186] This is similar to the calculation of the cap on ACO prospective HCC risk score growth finalized in the CY 2023 PFS (87 FR 69932 through 69946) and codified in §§ 425.605(a)(1)(ii)(A) and 425.610(a)(2)(ii)(A).

-- The aggregate regional prospective HCC risk score growth (calculated in step 3), and

-- The non-market share adjusted cap (calculated first in this step).

This adjustment of the cap on regional risk score growth using the ACO's aggregate market share creates a sliding scale. Assuming that an ACO has aggregate regional prospective HCC risk score growth above the non-market share adjusted cap, an ACO with close to 0 percent aggregate market share would receive a market share adjusted cap on regional risk score growth close to the aggregate growth in regional demographic risk scores plus 3 percentage points and an ACO with 100 percent aggregate market share would receive a market share adjusted cap on regional risk score growth equal to the aggregate regional prospective HCC risk score growth calculated in step 3 (which is effectively no cap at all). Under this approach, as an ACO's aggregate market share increases, so does the cap on the ACO's regional risk score growth, ultimately limiting the potential increase to the regional update factor for ACOs with high market share.

• *Step 5:* Determine the regional risk score growth cap adjustment factor. First, we would determine if the ACO's regional risk score growth is subject to a cap by comparing the ACO's aggregate regional prospective HCC risk score growth (calculated in step 3) to the market share adjusted cap on regional risk score growth (calculated in step 4).

++ If the aggregate regional prospective HCC risk score growth does not exceed the cap on regional risk score growth, the ACO's regional risk score growth would not be subject to the cap. For these ACOs we would set the risk score growth cap adjustment factor equal to 1 for each Medicare enrollment type (which is effectively no adjustment).

++ If the aggregate regional prospective HCC risk score growth exceeds the market share adjusted cap, the ACO's regional risk score growth is subject to the cap. For these ACOs we would next determine whether the cap on regional risk score growth applies for each Medicare enrollment type. To do this, we would compare regional prospective HCC risk score growth for each Medicare enrollment type (calculated in step 3) with the market share adjusted cap (calculated in step 4). If the regional risk score growth for a Medicare enrollment type does not exceed the cap, the enrollment type is not subject to the cap and the regional risk score growth cap adjustment factor for that Medicare enrollment type is set equal to 1 (effectively no adjustment). Otherwise, the Medicare enrollment type is subject to the cap and we would set the adjustment factor for the Medicare enrollment type equal to the regional prospective HCC risk score growth for the Medicare enrollment type (calculated in step 3) divided by the market share adjusted cap calculated in step 4. In this case, the adjustment factor for the Medicare enrollment type would represent a measure of how far above the cap the regional prospective HCC risk score growth is.

Table 32 provides a numeric example of the calculation of the regional risk score growth cap adjustment factor for a hypothetical ACO that is determined to be subject to the market share adjusted cap. Table 32 begins at the end of step 2 of the calculation, and therefore only reflects regional-level calculations and does not include the county-level calculations:

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TABLE 32: Example of Calculation of the Regional Risk Score Growth Cap Adjustment Factor for a Hypothetical ACO

Regional Level Measure	ESRD	Disabled	Aged/dual	Aged/non-dual	Weighted Average
Results of Step 2 (Regional Risk Scores (Calculation not shown))					
[A] BY3 Prospective HCC Risk Scores	1.027	1.016	1.037	1.006	
[B] PY Prospective HCC Risk Scores	1.075	1.049	1.043	1.053	
[C] BY3 Demographic Risk Scores	1.016	0.996	1.047	1.007	
[D] PY Demographic Risk Scores	0.962	1.012	1.054	0.983	
Step 3 (Determine growth in aggregate risk scores)					
[E] Prospective HCC Risk Ratio, [B] / [A]	1.047	1.032	1.006	1.047	
[F] Demographic Risk Ratio, [D] / [C]	0.947	1.016	1.006	0.977	
[G] Risk Score Weights (ACO performance year assigned person years multiplied by regionally adjusted historical benchmark expenditures, as a proportion)	0.010	0.090	0.150	0.750	
[H] Weighted Average HCC Risk Ratio, weighted average of [E] using weights [G]					1.039
[I] Weighted Average Demographic Risk Ratio, weighted average of [F] using weights [G]					0.984
Step 4 (Determine the cap on regional risk score growth)					
[J] Non-market Share Adjusted Cap, [I] + 0.030					1.014
[K] Market Share Weights (ACO performance year assigned person years, as a proportion)	0.007	0.085	0.120	0.788	
[L] ACO Market Share	0.150	0.200	0.180	0.300	
[M] Weighted Average Market Share, weighted average of [L] using weights [K]					0.276
[N] Market Share Adjusted Cap, [J]+([M]*([H]-[J])), Note that [H]-[J] is subject to a floor of 0					1.021
Step 5 (Determine the regional risk score growth cap adjustment factor)					
[O] Is the ACO Subject to Cap? [H] > [N]?					Yes
[P] Is the Enrollment Type Subject to Cap, If [O] = Yes, is [E]>[N]? If [O] = No, then No	Yes	Yes	No	Yes	
[Q] Regional Risk Score Growth Cap Adjustment Factor, If [P] =Yes, then [E]/[N], else 1	1.025	1.011	1.000	1.025	

Table Note: This numeric example shows only three decimal places and so attempting to replicate the calculations may result in slight differences due to rounding. In actual calculations all decimal places would be used.

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In this example, the hypothetical ACO was in a regional service area with aggregate prospective HCC risk score growth (a weighted average risk ratio of 1.039, refer to row [H]) above the market share adjusted cap of 1.021 (refer to row [N]). The ACO's regional prospective HCC risk score growth (shown in row [E]) was above this cap for three of the four Medicate enrollment types (all but the aged/dual eligible Medicare enrollment type). Therefore, the regional risk score growth cap adjustment factor (refer to row [Q]) calculated for those three capped Medicare enrollment types was above one, and the regional risk score growth cap adjustment factor calculated for the one uncapped Medicare enrollment type was equal to one. Once the regional risk score growth cap adjustment factors are multiplied by the original regional update factors used to update the historical benchmark between BY3 and the performance year, the regional update factor would increase for the three capped Medicare

enrollment types. For example, if the original regional update factor for the ESRD Medicare enrollment type was 0.976, then the final regional ESRD update factor after the application of the regional risk score growth cap adjustment factor would be 1.000 (the product of 0.976 and the regional risk score growth cap adjustment factor of 1.025). There would be no change to the original regional update factor for the uncapped aged/dual eligible Medicare enrollment type as it would be multiplied by one. Because of the increase in original regional update factor for the three capped Medicare enrollment types, this hypothetical ACO would have a higher updated benchmark under this proposed policy than under current policy.

However, if an ACO was in a regional service area with aggregate prospective HCC risk score growth that was not above the regional risk score growth cap, the regional risk score growth cap adjustment factor for all Medicare enrollment types would be equal to one, thus resulting in no change to the original regional update factor for any Medicare enrollment type and therefore no change to the ACO's updated benchmark compared to current policy.

We believe this proposed policy would help increase the accuracy of the regional update factor for ACOs operating in regional service areas with high risk score growth, including those serving more medically complex beneficiaries, therefore increasing incentives for ACOs to form or continue participation in such areas. At the same time, we believe that incorporating the market share adjustment helps to mitigate concerns related to coding intensity for ACOs with high market share and thus a relatively high level of influence over risk scores in the ACOs regional service area as discussed in section III.G.4.b.(1) of this proposed rule and would therefore protect the Trust Funds by continuing to limit incentives for this behavior.

We simulated the impact of the proposed policy using PY 2021 financial reconciliation data for ACOs in agreement periods beginning on or after July 1, 2019. This simulation found that 38 of the 332 ACOs (11 percent) would have been subject to the cap on regional risk score growth determined in step 4 of the proposed methodology and therefore would have had a higher regional update factor than under current policy for at least one Medicare enrollment type. Thirty-six of those 38 ACOs were subject to the 3 percent cap on their own risk score growth for at least one enrollment type in actual PY 2021 results. Table 33 shows the percentage of ACOs determined to be subject to the cap on regional risk score growth for each Medicare enrollment type and the average increase in the regional update factor for that enrollment type among those ACOs.

TABLE 33: Share of ACOs Subject to Regional Risk Score Growth Cap and Average Increase in Regional Update Factor among those ACOs by Medicare Enrollment Type

	ESRD	Disabled	Aged/Dual	Aged/Non-Dual
Share of ACOs Capped in Simulation	2%	5%	10%	11%
Average Change in Regional Update Factor	0.011	0.015	0.035	0.016

While this modeling shows that only a small proportion of ACOs would have benefitted from this policy in PY 2021, our analyses have also shown that this proportion is predicted to increase as more ACOs advance farther into their 5-year agreement period. This is supported by the finding that ACOs in the simulation were significantly more likely to be impacted if their agreement period started in 2019 with a BY3 of 2018 (16 percent) than if their agreement period started in 2020 with a BY3 of 2019 (6 percent).[187] Because the analysis of PY 2021 data demonstrates that circumstances like the PHE for COVID–19 and progression along a 5-year agreement period can interact to increase the share of ACOs in regional service areas with aggregate regional risk score growth above the cap, we have determined that our initial concerns about creating adverse incentives for coding behavior by capping regional risk score growth, as discussed in section III.G.4.b.(1) of this proposed rule, are outweighed by the potential harm to ACOs in regions with high risk score growth, particularly when such growth is not due to the ACO's own coding activities. Additionally, we believe the market share adjustment to the cap on regional risk score growth will limit overly advantaging ACOs with high market share if they participate in coding initiatives.

Table 34 displays information on the impact of the market share adjustment on the cap on regional risk score growth within our simulation of the proposed policy in PY 2021 for the ACOs with the minimum, median, and maximum aggregate market share that were found to be subject to the cap on regional risk score growth.

[187] While analysis of average FFS risk score changes at the hospital referral region (HRR) level further supports the assumption that more ACOs would be impacted toward the end of their 5-year agreement period, such analysis also indicates that variation from the PHE for COVID–19 likely accentuated this phenomenon in the simulation on PY2021 data. For this reason, the finding in the PY2021 simulation that 16 percent of 2019 starters were impacted is likely indicative of an upper bound for the share of ACOs potentially impacted by PY5 in agreement periods that start in 2024 or later (that is, where the impact of the PHE for COVID–19 is minimal in BY3 relative to the BY3s in this simulation).

TABLE 34: Aggregate Market Share and Impact of Market Share Adjustment on Cap on Regional Risk Score Growth among ACOs Subject to Regional Risk Score Growth Cap (N=38)

	Aggregate Market Share (proportion)	Non-Market Share Adjusted Cap	Market Share Adjusted Cap	Difference between Market Share Adjusted and Non-Market Share Adjusted Cap
Minimum	0.009	1.036	1.036	<0.001
Median	0.127	1.034	1.034	0.001
Maximum	0.536	1.008	1.028	0.020

Note: The minimum, median, and maximum refer to the minimum, median and maximum aggregate market share. The non-market share adjusted cap, market share adjusted cap, and difference between market share adjusted and non-market share adjusted cap represent data from the ACOs with the minimum, median, and maximum market shares. Because there are an even number of impacted ACOs, there are two ACOs comprising the median of 0.127. These two ACOs have the same non-market share adjusted and market share adjusted caps and have been combined into a single row for simplicity.

Based on this data in Table 34, the majority of ACOs found to be impacted in this simulation had a relatively small aggregate market share, with a median of about 13 percent. Because of this, the median increase to the cap on regional risk score growth from the market share adjustment was small (0.001). (This is both the median increase among all 38 impacted ACOs and the increase for the impacted ACO with the median market share). Further analysis showed that results were similar among both rural and urban ACOs. Of the 38 impacted ACOs, 34 were classified as urban and had a median aggregate market share of about 12 percent. The remaining four impacted ACOs were rural ACOs with a median aggregate market share of about 24 percent. While the market share was higher on average among rural ACOs, average market share for both types of ACOs was under 25 percent and both groups had only a small median increase to the cap on regional risk score growth from the market share adjustment of 0.001.[188]

ACOs with a larger aggregate market share received a larger increase in the cap on regional risk score growth due to the market share adjustment. For example, in Table 34, the ACO with the highest market share of 53.6 percent (an ACO that has a regional service area in an urban area), had a 20 percent increase in its cap from the market share adjustment, going from a non-market share adjusted cap of 1.008 to an adjusted cap of 1.028. We believe that, while the impact of the market share adjustment on the cap on regional risk score growth will be small for the majority of ACOs, this market share adjustment is important to address both our own concerns related to incentives for coding intensity and the similar concerns raised by MedPAC in the CY 2023 PFS final rule, as discussed in section III.G.4.b.(1) of this proposed rule. The market share adjustment to the cap limits the adverse coding incentives that can arise when allowing larger benchmark increases when an ACO increases its coding, especially for ACOs with high market share. Specifically, ACOs with high market share will still have a disincentive to engage in coding initiatives, as these initiatives could increase risk score growth in their regional service area and potentially decrease the value of the regional component of their update factor.

Apart from the market share adjustment, the calculation of the proposed cap on regional risk score growth between BY3 and the performance year is calculated in the same way as the aggregate demographics plus 3 percent cap on ACO risk score growth under §§ 425.605(a)(1)(ii)(A) and 425.610(a)(2)(ii)(A). Specifically, the cap is calculated as the aggregate growth in regional demographic risk scores between BY3 and the performance year plus 3 percentage points, prior to application of the market share adjustment. Additionally, as a result of incorporating the risk adjustment into the regional update factor at the county level, the current methodology does not directly calculate a regional risk ratio that can be directly modified. The proposed approach of modifying the regional update factor by multiplying by an adjustment factor achieves the goal of reducing the impact of regional risk score growth while leaving the existing methodology for calculating risk-adjusted regional expenditures intact.

As we have explained in earlier rulemaking (see 87 FR 69887 and 69888), we have used our authority under section 1899(i)(3) of the Act to adopt a three-way blended benchmark update factor (weighted one-third ACPT, and two-thirds national-regional blend) for agreement periods beginning on January 1, 2024, and in subsequent years, in place of an update factor based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program as called for in section 1899(d)(1)(B)(ii) of the Act. Therefore, the proposed changes to the regional component of the three-way blended update factor described in this section of this proposed rule would similarly require continued use of our statutory authority under section 1899(i)(3) of the Act. Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and program expenditures under the alternative methodology would be equal to or lower than those that would result under the statutory payment model. We believe the changes to the methodology for updating the benchmark that we are proposing pursuant to section 1899(i)(3) of the Act would improve the quality and efficiency of items and services furnished under the Medicare Program. More specifically, we believe that the proposed changes to the regional component of the update factor would—

[188] For this analysis, ACOs were classified as rural if the plurality of their assigned beneficiaries resided in either micropolitan or noncore counties and urban if the plurality of their assigned beneficiaries resided in either large central metro, large fringe metro, medium metro, or small metro counties as defined by The United States Census Bureau and the Office of Management and Budget (OMB).

in the context of the downward effects on the benchmark resulting from elevated variation in regional average prospective HCC risk score growth as shown in the PY 2021 analysis—reinforce the incentive for ACOs to enter and remain in the Shared Savings Program, particularly in regions with changing populations. Moreover, we believe that the proposed approach, by encouraging ACOs to enter and continue participation in the Shared Savings Program, would lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs have an incentive to perform well on quality measures in order to maximize the shared savings they may receive. In addition, as discussed in the Regulatory Impact Analysis (section VII.E.10. of this proposed rule), we believe the proposed changes to the regional component of the three-way blended update factor, in combination with the other proposals for which we must use our authority under section 1899(i)(3) of the Act, would result in a marginal impact that is estimated to result in $330 million in lower net spending over the 10-year projection window, which supports our finding that the relatively minor changes to program spending resulting from these proposed changes would not violate the requirements of section 1899(i)(3)(B) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We propose to revise the Shared Savings Program regulations governing the calculation of the regional growth rate when updating the historical benchmark between BY3 and the performance year at § 425.652(c) to incorporate a regional risk score growth cap adjustment factor. We also propose to add a new section to the regulations at § 425.655 to describe the calculation of the adjustment factor.

We seek comment on the proposed changes to calculation of the regional component of the update factor for agreement periods beginning on or after January 1, 2024.

c. Mitigating the Impact of the Negative Regional Adjustment on the Benchmark To Encourage Participation by ACOs Caring for Medically Complex, High-Cost Beneficiaries

(1) Background

In earlier rulemaking we have discussed our use of the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate'' in order to adjust ACO historical benchmarks to reflect FFS expenditures in the ACO's regional service area (81 FR 37962). We initially established a regional adjustment in a benchmark rebasing methodology that applied to ACOs entering a second agreement period beginning on January 1, 2017, January 1, 2018, or January 1, 2019 (§ 425.603(c) through (g)), before modifying our policy to apply this adjustment program wide beginning with agreement periods starting on July 1, 2019, and in subsequent years (§ 425.601(a)(8)). In the CY 2023 PFS final rule (87 FR 69915 through 69923) we modified the way we would calculate the regional adjustment for ACOs in agreement periods starting on January 1, 2024, and in subsequent years (§ 425.656). We also finalized a policy that would modify the way we would apply the regional adjustment to the benchmark that would also take into account a new adjustment for prior savings that would be available to eligible ACOs (§ 425.652(a)(8)).

In accordance with § 425.601(a)(8), for ACOs in agreement periods beginning on or after July 1, 2019 and before January 1, 2024, we adjust historical benchmark expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark (referred to herein as the ''regional adjustment''). The percentage applied in calculating the regional adjustment depends on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment, according to the phase-in schedule of applicable weights. We cap the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to positive or negative 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3 (§ 425.601(a)(8)(ii)(C)) (referred to herein as positive or negative 5 percent of national per capita FFS expenditures for assignable beneficiaries, and as the ''symmetrical cap,'' terms which we consider to be synonymous). We then apply the capped regional adjustment for each Medicare enrollment type by adding it to the historical benchmark expenditure for that enrollment type. A positive regional adjustment for a given Medicare enrollment type increases the benchmark for that enrollment type, whereas a negative regional adjustment decreases the benchmark for that enrollment type.

With the policies finalized in the CY 2023 PFS final rule (87 FR 69915 through 69923), we sought to reduce the impact of negative regional adjustments in several ways for agreement periods beginning on January 1, 2024, and subsequent years. First, we finalized a policy that replaced the negative 5 percent cap on the negative regional adjustment with a negative 1.5 percent cap. Under this policy, we would continue to cap positive adjustments for each Medicare enrollment type at a dollar amount equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for that enrollment type but would cap negative adjustments for each enrollment type at a dollar amount equal to negative 1.5 percent of national per capita FFS expenditures for assignable beneficiaries for that enrollment type. Additionally, after applying the negative 1.5 percent cap, we would apply an offset factor that would gradually decrease the negative regional adjustment amount for a given Medicare enrollment type as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases. Finally, for an ACO eligible for the prior savings adjustment for which the regional adjustment expressed as a single value (based on taking a person year weighted average across the four Medicare enrollment types) is negative, we would further offset the regional adjustment by the prior savings adjustment. In the CY 2023 PFS final rule (87 FR 69919) we expressed our belief that by reducing the impact of negative regional adjustments, these policies would incentivize ACOs that serve high-cost beneficiaries to join or

continue to participate in the Shared Savings Program.

These policies to reduce the impact of negative regional adjustments are reflected in several new sections of the regulations. Section 425.652 is the main provision that describes the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, including the interaction of the regional adjustment and the prior savings adjustment. Sections 425.656 and 425.658 provide additional detail on the calculations of the regional adjustment and the prior savings adjustment, respectively.

Table 35 illustrates how the caps to the regional adjustment would be calculated and applied to positive and negative regional adjustments at the Medicare enrollment type level under the policy finalized in the CY 2023 PFS final rule. Note that the uncapped regional adjustment values would be calculated using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending as compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d). For example, if an ACO is considered to have lower spending compared to the ACO's regional service area, and it is the ACO's first agreement period subject to the regional adjustment, we would use a weight of 35 percent when applying the regional adjustment. If an ACO is considered to have higher spending compared to the ACO's regional service area, and it is the ACO's first agreement period subject to the regional adjustment, we would use a weight of 15 percent when applying the regional adjustment.

TABLE 35: Hypothetical Example of Cap on Regional Adjustment

Medicare Enrollment Type	Medicare Enrollment Type Proportion	Uncapped Regional Adjustment ($)	Positive Regional Adjustment Cap: - 5% of National Assignable Per Capita Expenditures ($)	Negative Regional Adjustment Cap: -1.5% of National Assignable Per Capita Expenditures ($)	Capped Regional Adjustment ($)
ESRD	0.015	932	4,437	-1,331	932
Disabled	0.190	-185	639	-192	-185
Aged/dual	0.100	258	974	-292	258
Aged/non-dual	0.695	-307	553	-166	-166
Weighted Average		-209			-111

The hypothetical ACO in this example has a mix of positive and negative regional adjustments across the four enrollment types. The ACO's uncapped aged/non-dual eligible adjustment is outside the negative 1.5 percent cap and thus changes from −$307 to −$166 when the cap is applied. The ACO's adjustments for the other three enrollment types are all within the applicable positive or negative caps and are thus unaffected. The ACO's overall weighted average regional adjustment (calculated by multiplying the adjustment for each enrollment type by the corresponding enrollment type proportion and then summing across the four enrollment types) changes from −$209 to −$111 when the negative regional adjustment cap is applied, reducing the per capita impact of the negative regional adjustment by $98.

Under the methodology adopted in the CY 2023 PFS final rule (87 FR 69917 and 69920), after we apply the caps, we next apply an offset factor to any negative regional adjustments at the enrollment type level. The offset factor is based on the following: [A] the ACO's overall proportion of BY3 assigned beneficiaries that are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) [189] and [B] the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types.[190] Before taking this weighted average, the risk score for each enrollment type is first renormalized by dividing by the national mean risk score for the assignable FFS population for that enrollment type identified for the calendar year corresponding to BY3. Specifically, the offset factor is calculated as:

Offset factor = [A] + ([B] − 1)

We apply the offset factor, which is subject to a minimum of zero and a maximum of one, by subtracting its value from 1 and multiplying this difference by the negative regional adjustment for each Medicare enrollment type, calculated as:

Final regional adjustment = Negative regional adjustment × (1 − Offset factor)

The higher an ACO's proportion of dually eligible beneficiaries or the higher its risk score, the larger the offset factor would be and the larger the reduction to the overall negative regional adjustment. If the offset factor is equal to the maximum value of one, the ACO would not receive a negative regional adjustment for any enrollment type, because each negative adjustment would be multiplied by a value of 1 minus the offset factor, or 0. For these ACOs, the overall weighted average regional adjustment would either be 0 (if the ACO had negative adjustments for all four enrollment types prior to the application of the offset factor) or positive (if the ACO had a mix of positive and negative adjustments at the

[189] In computing this proportion, we use for each beneficiary the fraction of the year (referred to as person years) in which they were eligible for the aged/dual eligible enrollment type or for which they were eligible for the ESRD or disabled enrollment type and dually eligible for Medicare and Medicaid.

[190] In computing this weighted average, we apply a weight to the risk score for BY3 for an enrollment type that is equal to the product of the ACO's BY3 per capita expenditures for that enrollment type and the ACO's BY3 person years for that enrollment type.

enrollment type level prior to the application of the offset factor). If the offset factor is equal to the minimum value of zero, the ACO would receive no benefit from the offset factor.

To illustrate how the offset factor would be calculated and applied, assume that the hypothetical ACO from Table 35 had a proportion of dually eligible beneficiaries of 0.130 and a weighted average prospective HCC risk score for BY3 of 1.240. The offset factor for this ACO would be calculated as:

Offset factor = 0.130 + (1.240 − 1) = 0.370

This factor would be applied as illustrated in Table 36 by multiplying the negative regional adjustment for each applicable Medicare enrollment type by 1 minus the offset factor or 0.630.

TABLE 36: Hypothetical Example of Offset Factor Applied to Negative Regional Adjustments

Medicare Enrollment Type	Enrollment Proportion	Capped Regional Adjustment (Before Offset) ($)	Offset Factor	1 – Offset Factor	Final Regional Adjustment ($)
ESRD	0.015	932	N/A	N/A	932
Disabled	0.190	-185	0.370	0.630	-117
Aged/dual	0.100	258	N/A	N/A	258
Aged/non-dual	0.695	-166	0.370	0.630	-105
Weighted Average		-111			-55

Here, the offset factor is applied to the regional adjustments for the disabled and aged/non-dual eligible populations, as both are negative, but not to the regional adjustments for the ESRD and aged/dual eligible populations, which are both positive. Taking the weighted average across the enrollment types following application of the offset factor shows that the ACO's overall weighted regional adjustment changes from −$111 before the offset to −$55 after the offset, further reducing the per capita impact of the negative regional adjustment by $56. The overall per capita impact of both the cap and offset factor for this ACO would be $154.

In the CY 2023 PFS final rule (87 FR 69918 and 69921) we presented simulations of the combined impact of the cap and offset factor relative to the symmetrical positive and negative 5 percent cap then in place for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. The results of these simulations, which used data from PY 2020 historical benchmarks for ACOs in agreement periods starting on or after July 1, 2019, and from PY 2022 historical benchmarks for ACOs starting an agreement period on January 1, 2022, found the negative regional adjustment for almost every ACO that had an overall negative regional adjustment in the PY 2020 and PY 2022 data under the symmetrical cap would have been reduced (or eliminated), with an average per capita impact of approximately $114 for PY 2020 and $48 for PY 2022. ACOs with higher weighted average BY3 prospective HCC risk scores and higher proportions of dually eligible Medicare and Medicaid beneficiaries had overall greater reductions in their negative regional adjustments. Four ACOs in the PY 2020 simulation and one in the PY 2022 simulation had an offset factor of 1, meaning they would have received a full offset to their negative regional adjustments.

Under a separate policy also finalized in the CY 2023 PFS final rule, an ACO beginning an agreement period on January 1, 2024, and in subsequent years that is a renewing or re-entering ACO may be eligible to receive an adjustment to its benchmark to account for savings generated in performance years that correspond to the benchmark years of its new agreement period. A full discussion of this policy can be found in that earlier rulemaking (87 FR 69899 through 69915). The policy was designed such that an eligible ACO would receive the higher of its overall positive regional adjustment or its prior savings adjustment, or a combination of the two if its overall regional adjustment is negative and it had prior savings. ACOs ineligible for the prior savings adjustment would receive the regional adjustment (computed as described earlier in this section applying a 5 percent cap on positive regional adjustments and a −1.5 percent cap and offset factor on negative regional adjustments). Specifically, if the regional adjustment, expressed as a single value, is positive, the ACO would receive a final adjustment equal to the higher of the regional adjustment or an adjustment based on the ACO's prior savings (see § 425.652(a)(8)(iii)(B)). If the regional adjustment, expressed as a single value, is negative, we would calculate the final adjustment as described in § 425.652(a)(8)(iii)(A), with the ACO receiving either a smaller negative regional adjustment or a positive adjustment for prior savings depending on the relative size of the negative regional adjustment and the ACO's pro-rated prior savings.

Based on further consideration, we believe it is important and timely to revisit the policy that allows for negative adjustments to be applied in establishing the benchmark for ACOs. While we did not consider eliminating negative regional adjustments program-wide in CY 2023 PFS rulemaking, one commenter noted that there is an argument for doing so. We believe further mitigating the impact of the negative regional adjustment for ACOs with high-cost populations, thereby resulting in higher benchmarks for ACOs compared to the recently finalized methodology, could further bolster the business case for Shared Savings Program participation by such ACOs.

As we discussed in the CY 2023 PFS proposed rule (87 FR 46161), there is evidence that certain aspects of the program's benchmarking methodology, notably the regional adjustment to the benchmark, may deter participation among ACOs with spending above their regional service area including those serving medically complex, high-cost populations. High-cost ACOs are underrepresented in the Shared Savings Program, with around 86 percent of all participating ACOs receiving an overall

positive regional adjustment in PY 2022 indicating that a majority of ACOs are lower spending than their regional service area. We also observed that ACOs that received an overall negative regional adjustment for PY 2022 were less likely to continue participation in the program in PY 2023 than were ACOs that received an overall positive regional adjustment, with 22 percent of ACOs with a negative overall adjustment leaving the program compared to 12 percent of ACOs with a positive overall adjustment. Since PY 2017 the overall annual average share of ACOs that leave the program has been 12 percent. A recent academic study also found evidence suggesting selective participation among ACOs in response to the original adoption of a regional adjustment in 2017, with the composition of ACOs between 2017 to 2019 increasingly shifting to providers with lower preexisting levels of spending.[191] The authors attributed these changes to a combination of the entry of new ACOs with lower baseline spending, the exit of higher-spending ACOs, and the reconfiguration of ACO participant lists to favor lower-spending practices among ACOs continuing participation in the program.

Relatedly, we have observed that negative regional adjustments may make it more difficult for ACOs to succeed in the program financially. Between PY 2017, when regional adjustments were first introduced in the Shared Savings Program, and PY 2021, ACOs that received negative regional adjustments have been consistently less likely to share in savings than ACOs that received positive regional adjustments. For example, in PY 2021 we observed that 37 percent of ACOs that received a negative regional adjustment shared in savings compared to 63 percent among those with a positive adjustment.

We believe that eliminating the possibility that an ACO will receive an overall negative regional adjustment to its benchmark in combination with the other elements of the benchmarking methodology finalized in the CY 2023 PFS final rule, would work together to further our efforts to ensure sustainability of the benchmarking methodology. More specifically, we believe this policy change would further encourage continued participation among high-cost ACOs that serve medically complex beneficiaries by eliminating the potential of a lower benchmark due to an overall negative regional adjustment. It may also encourage ACOs serving such populations that may have otherwise been discouraged from participating in the Shared Savings Program by the idea of a lower benchmark to join. The implementation of this policy would allow ACOs to serve the most vulnerable populations while lessening the concern of how this may affect their performance in the program. We believe that program participation by ACOs serving these populations has the potential, over time, to produce cost savings for the Medicare Trust funds by improving care coordination and quality of care for such beneficiaries.

Additionally, we believe that eliminating overall negative regional adjustments could further incentivize greater participation among ACOs whose ACO participants have historically been less efficient than other providers and suppliers in their regions. Such ACOs may have the greatest potential to generate cost savings for the Medicare Trust Funds by adopting more efficient practices, therefore we believe that their participation in the program should not be discouraged.

(2) Proposed Revisions

In light of these considerations, we are proposing to modify the policies we adopted in the CY 2023 PFS final rule so as to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. Specifically, we are proposing the following approach to calculate and apply the regional adjustment, or the regional adjustment in combination with the prior savings adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2024, and in subsequent years:

- We would continue to calculate the original uncapped regional adjustment by Medicare enrollment type using the applicable percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d).
- We would continue to apply the 5 percent cap on positive regional adjustments and the −1.5 percent cap and offset factor on negative regional adjustments at the enrollment type level, as finalized in the CY 2023 PFS final rule and described in § 425.656(c). For the performance year beginning on January 1, 2025, and subsequent performance years, the national assignable fee-for-service population used to calculate the caps would reflect the revised definition of assignable beneficiary that incorporates the expanded window for assignment as proposed in section III.G.3.a of this proposed rule, if finalized.
- After applying the cap and offset factor (if applicable), we would express the regional adjustment as a single per capita value by calculating a person year weighted average of the Medicare enrollment type-specific regional adjustment values.
- If the ACO's regional adjustment amount (expressed as a single per capita value) is positive, the ACO would receive a regional adjustment, according to the approach we finalized in the CY 2023 PFS final rule. That is, we would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type. If the ACO is also eligible for a prior savings adjustment, the ACO would receive the higher of the two adjustments. If the regional adjustment amount (expressed as a single per capita value) is higher, we would apply the enrollment type-specific regional adjustment amounts separately to the historical benchmark expenditures for each Medicare enrollment type. If the prior savings adjustment is higher, we would apply the adjustment in the manner finalized in the CY 2023 PFS final rule as a flat dollar amount applied separately to the historical benchmark expenditures for each Medicare enrollment type.
- If the ACO's regional adjustment amount (expressed as a single per capita value) is negative, the ACO would receive no regional adjustment to its benchmark for any enrollment type. If the ACO is eligible for a prior savings adjustment, it would receive the prior savings adjustment as its final adjustment, without any offsetting reduction for the negative regional adjustment.

Under the proposed approach, ACOs that would face a negative overall adjustment to their benchmark based on the methodology adopted in the CY 2023 PFS final rule would benefit, as they would now receive no downward adjustment. Additionally, ACOs that have a negative regional adjustment amount (expressed as a single value) and are eligible for prior savings adjustment under the policy adopted in the CY 2023 PFS final rule (§ 425.658) would also be expected to benefit from the proposed policy. Specifically, these ACOs could receive a larger positive adjustment to their benchmark or a positive adjustment instead of a negative adjustment, as we would no

[191] Lyu P, Chernew M, McWilliams J. Benchmarking Changes And Selective Participation In The Medicare Shared Savings Program. *Health Affairs*. May 1, 2023. Available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01061*.

longer offset the prior savings amount by the negative regional adjustment amount when determining the final adjustment that would apply to the ACO's benchmark as described in the current regulations in § 425.652(a)(8)(iii)(A).[192] We believe that by increasing the potential benefit of the prior savings adjustment in this manner, our proposed policy would be responsive to the comments discussed in the CY 2023 PFS final rule recommending that CMS make the prior savings adjustment more favorable, particularly for ACOs serving high-risk populations (see 87 FR 69910 through 69914).

[192] For examples of the calculation of the final adjustment when an ACO is eligible for a prior savings adjustment and the overall regional adjustment is negative under the policy adopted in the CY 2023 PFS final rule, please refer to Tables 65 and 66 of the CY 2023 PFS final rule (87 FR 69904 and 69905). In Table 65 the hypothetical ACO receives a positive final adjustment and in Table 66 a negative final adjustment.

Importantly, no ACO would be made worse off under the proposed policy. ACOs that have an overall positive regional adjustment amount would continue to receive the same adjustment to their benchmark as they would under the methodology finalized in the CY 2023 PFS final rule calculated and applied as described in the current regulations at §§ 425.656 and 425.652(a)(8), respectively. For these ACOs, the regional adjustment would continue to reflect the percentage phase-in weight based on whether the ACO has lower or higher spending compared to its regional service area and the ACO's agreement period subject to a regional adjustment as described in § 425.656(d) and we would continue to allow negative adjustments to be applied at the enrollment type level for those ACOs that receive a positive overall regional adjustment. We believe this is appropriate because these ACOs would continue to receive a positive overall adjustment to their benchmark and thus should already have greater incentive to join or continue participation in the program than ACOs that might otherwise face an adjustment that reduces their benchmark.

Tables 37 and 38 present hypothetical examples to demonstrate how we would determine the final adjustment to an ACO's benchmark under the proposed policy. Both tables include two hypothetical ACOs. The first ACO, ACO A, is the same hypothetical ACO as illustrated in Tables 35 and 36 within this section and has an overall negative regional adjustment. The second ACO, ACO B, has an overall positive regional adjustment. Table 37 assumes that both ACOs are ineligible for a prior savings adjustment, whereas Table 38 shows how the calculation would change if both ACOs were eligible for such an adjustment.

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TABLE 37: Hypothetical Examples of the Determination of the Final Adjustment to the Benchmark Assuming ACOs are Not Eligible for a Prior Savings Adjustment

Calculation Step	ACO A: Negative Regional Adjustment	ACO B: Positive Regional Adjustment
Historical benchmark expenditures by enrollment type, before adjustment ($) [A]:		
ESRD	90,000	101,000
Disabled	16,000	12,000
Aged/dual	18,000	19,000
Aged/non-dual	10,000	9,000
Enrollment proportion [B]		
ESRD	0.015	0.005
Disabled	0.190	0.100
Aged/dual	0.100	0.050
Aged/non-dual	0.695	0.845
Regional adjustment by enrollment type, reflecting the applicable phase-in weight and after cap and offset (if applicable) ($) [C]:		
ESRD	932	-1,331
Disabled	-117	158
Aged/dual	258	-210
Aged/non-dual	-105	179
Regional adjustment (expressed as single value) ($) [D] = Sum of [B] x [C]	-55	150
Final adjustment ($) [E]= N/A if [D] is negative, otherwise [D]	N/A	150
Historical benchmark expenditures by enrollment type, after adjustment ($) [F] = [A] if [E] is N/A, otherwise [A] + [C]		
ESRD	90,000	99,669
Disabled	16,000	12,158
Aged/dual	18,000	18,790
Aged/non-dual	10,000	9,179

In Table 37, because ACO A had an overall negative regional adjustment and was not eligible for a prior savings adjustment, the ACO ultimately receives no adjustment, upward or downward, to its benchmark. For ACO B, whose overall regional adjustment is positive, the final adjustment is the regional adjustment, which is applied by adding the regional adjustment specific to each enrollment type (reflecting the percentage weight determined for the ACO and after the application of the cap and offset factor, if applicable) to the ACO's pre-adjustment historical benchmark expenditures for that enrollment type.

TABLE 38: Hypothetical Examples of the Determination of the Final Adjustment to the Benchmark Assuming ACOs are Eligible for a Prior Savings Adjustment

	ACO A: Negative Regional Adjustment	ACO B: Positive Regional Adjustment
Historical benchmark expenditures by enrollment type, before adjustment ($) [A]:		
ESRD	90,000	101,000
Disabled	16,000	12,000
Aged/dual	18,000	19,000
Aged/non-dual	10,000	9,000
Enrollment type proportions [B]		
ESRD	0.015	0.005
Disabled	0.190	0.100
Aged/dual	0.100	0.050
Aged/non-dual	0.695	0.845
Regional adjustment by enrollment type, reflecting the applicable phase-in weight and after cap and offset (if applicable) ($) [C]:		
ESRD	932	-1,331
Disabled	-117	158
Aged/dual	258	-210
Aged/non-dual	-105	179
Regional adjustment (expressed as single value) [D] = Sum of [B] x [C]	-55	150
Prior savings adjustment* ($) [E]	58	239
Final adjustment ($) [F]= [E] if [D] is negative, otherwise higher of [D] or [E]	58	239
Historical benchmark expenditures by enrollment type, after adjustment [G] = [A] + [C] if [E] = [D], otherwise [A] + [E] for each enrollment type		
ESRD	90,058	101,239
Disabled	16,058	12,239
Aged/dual	18,058	19,239
Aged/non-dual	10,058	9,239

*As provided in the proposed new provision at § 425.658(c)(1) of the regulations, the prior savings adjustment would be calculated as the lesser of 50 percent of the pro-rated positive average per capita savings amount, calculated as described in § 425.658(b)(3)(ii), and a cap equal to 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values.

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In Table 38, both ACO A and ACO B are eligible for a prior savings adjustment. Because ACO A has a negative overall regional adjustment, its final adjustment is automatically set equal to the prior savings adjustment of $58. The adjustment is applied as flat dollar amount by adding the $58 to the ACO's historical benchmark expenditures (row [A]) for each enrollment type. For ACO B, by contrast, the final adjustment is determined by comparing the regional adjustment amount (expressed as a single value) to the prior savings adjustment amount and using the higher of the two. In this case the ACO would receive a final adjustment equal to the prior savings adjustment of $239. Like with ACO A, this would be applied to the ACO's historical benchmark expenditures for each enrollment type as a flat dollar amount.

In revisiting simulations done with PY 2020 data described earlier in this section, there were 36 ACOs (of the 43 ACOs with a negative regional adjustment under the policy with the symmetrical cap) simulated to have a negative overall regional adjustment after the application of the cap and offset factor. Among these, 31 would not have been eligible for a prior savings adjustment and would have had this negative regional adjustment applied to their benchmark under the policy adopted in the CY 2023 PFS final rule. Under the new proposed policy, these ACOs would receive no adjustment to their benchmark. The average per capita benefit of eliminating the downward adjustment would be $30.

The remaining five ACOs would have been eligible for the prior savings adjustment. These ACOs would have received a positive final adjustment to their benchmark under the methodology adopted in the CY 2023 PFS final rule but would receive a larger positive adjustment under the new proposed

policy, with an average per capita increase of $26. This is because we would no longer be offsetting the prior savings amount by the negative regional adjustment as part of determining the final adjustment to the ACO's benchmark as would happen under the methodology finalized in the CY 2023 PFS final rule and codified at § 425.652(a)(8)(iii)(A).

In the PY 2022 simulation described earlier in this section, there were 26 ACOs (of the 27 ACOs with a negative regional adjustment under the policy with the symmetrical cap) that would have had a negative regional adjustment, expressed as a single per capita value, after the application of the policy adopted in the CY 2023 PFS final rule. Among these, 14 ACOs would not have been eligible for a prior savings adjustment and would have their full negative regional adjustment eliminated under the new proposed policy, with an average impact of $66. The remaining 12 ACOs that would have been eligible for a prior savings adjustment would see a larger positive adjustment under the proposed policy, with an average increase of $14.

Overall, we believe that the proposed changes to the calculation and application of the regional adjustment, including its interaction with the prior savings adjustment, would strengthen incentives for participation among ACOs that might otherwise be subject to a downward adjustment to their benchmark due to the negative regional adjustment. The proposed policy, if finalized, would not adversely impact any ACO's benchmark relative to the policy that was finalized in CY 2023 PFS final rule, all else being equal, but would tend to increase benchmarks for ACOs that have historically had higher spending than their regional service area. Based on our simulations using data from PY 2020 and PY 2022, the estimated average increase to the overall benchmark would be between 0.2 and 0.4 percent but could be larger in future years when more ACOs would be subject to higher phase-in weights for calculating the negative regional adjustment that would apply (alone or in combination with the prior savings adjustment) under the policy adopted in the CY 2023 PFS final rule. ACOs that would benefit from the proposed policy are likely to include those that serve high-cost, medically complex patients or those whose ACO participants have historically been less efficient than their regional counterparts but may have the potential to generate the greatest savings to Medicare through their participation in the Shared Savings Program.

We propose to implement the changes described in this section through revisions to §§ 425.652, 425.656, and 425.658. Specifically, within § 425.652, which is the section that sets forth the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, we propose revisions to § 425.652(a)(8). As revised, this provision would describe how we would determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. This provision would also establish that if an ACO is not eligible to receive a prior savings adjustment and has a regional adjustment, expressed as a single value that is negative or zero, the ACO will not receive an adjustment to its benchmark.

We propose to revise § 425.656 (which describes the calculation of the regional adjustment) and § 425.658 (which describes the calculation of the prior savings adjustment) to include certain elements of each calculation that were previously described in § 425.652(a)(8). Specifically, we propose to revise § 425.656 to redesignate paragraphs (d) and (e) as paragraphs (e) and (f) (respectively) and to specify in a new paragraph (d) that we would express the regional adjustment as a single value, and use this value in determining whether a regional adjustment or a prior savings adjustment would be applied to the ACO's benchmark in accordance with § 425.652(a)(8) (as revised under this proposed rule). We also propose modifications to update certain cross-references within § 425.656 for accuracy and consistency with the proposed revisions to the section.

We propose to revise § 425.658 to redesignate paragraph (c) as paragraph (d). We propose to add a new paragraph (c) under § 425.658 specifying that we would calculate the per capita savings adjustment as the lesser of 50 percent of the pro-rated average per capita savings amount (computed as described in § 425.658(b)(3)(ii)) and the cap equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for BY3 expressed as a single value by taking a person-year weighted average of the Medicare enrollment-type specific values. We propose to revise newly redesignated paragraph (d) of § 425.658 to specify CMS would compare the per capita prior savings adjustment with the regional adjustment, expressed as a single value as described in § 425.656(d), to determine the adjustment, if any, that would be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

Additionally, we propose to make the following conforming changes:

- In § 425.600(f)(4)(ii), we propose to remove the reference ''425.656(d)'' and add in its place the reference ''425.656(e)''.
- In § 425.611(c)(2)(iii), we propose to remove the reference ''§ 425.652(a)(8)(iv)'' and add in its place the reference ''§ 425.658(c)(1)(ii)''.
- In § 425.652(a)(9)(v), we propose to remove the wording that references CMS redetermining the adjustment to the benchmark based on ''a combination of'' the redetermined regional adjustment and the prior savings adjustment.
- In § 425.658(b)(3)(i), which specifies that the ACO is not eligible to receive an adjustment for prior savings if the average per capita amount computed in § 425.658(b)(2) is less than or equal to zero, we propose to remove the sentence: ''The ACO will receive the regional adjustment to its benchmark as described in § 425.656.''

We seek comment on these proposed changes.

d. Proposal To Modify the Prior Savings Adjustment

(1) Background

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period using the most recent available 3 years of expenditures for Parts A and B services for beneficiaries assigned to the ACO. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, as described in the CY 2023 PFS final rule (87 FR 69898 through 69915), we established a prior savings adjustment that will apply when establishing the benchmark for ACOs entering a second agreement period beginning on January 1, 2024, or in subsequent years, to account for the average per capita amount of savings generated during the ACO's prior agreement period.

The prior savings adjustment adopted in the CY 2023 PFS final rule is designed to adjust an ACO's benchmark to account for the average per capita amount of savings generated by the ACO across the 3 performance years prior to the start of its current agreement period for new and renewing ACOs. In the final rule, we explained that reinstituting a prior savings adjustment would be

broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance years corresponding to the benchmark years for the ACO's new agreement period. We also explained our belief that a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark.

In the CY 2023 PFS final rule, we explained that, in order to mitigate the potential for rebased benchmarks for ACOs that are lower-spending compared with their regional service area and that achieved savings in the benchmark period to become overinflated, we believed that adjusting an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment would be appropriate. Additionally, we believed it would be appropriate to use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area. We noted that this would permit ACOs that are subject to a negative regional adjustment, but that have generated savings in prior years, to receive a relatively higher benchmark.

Under the methodology finalized in the CY 2023 PFS final rule and codified at § 425.658 of the regulations, the prior savings adjustment that will apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, is calculated as follows:

- *Step 1:* Calculate total per capita savings or losses in each performance year that constitutes a benchmark year for the current agreement period. For each performance year we will determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. CMS will apply the following requirements in determining the amount of per capita savings or losses for each performance year:

++ The per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

++ If an ACO generated savings for a performance year but was not eligible to receive a shared savings payment for that year due to noncompliance with Shared Savings Program requirements, the per capita savings for that year will be set to zero.

++ For a new ACO that is identified as a re-entering ACO, per capita savings or losses will be determined based on the per capita savings or losses of the ACO in which the majority of the ACO participants in the re-entering ACO were participating.

- *Step 2:* Calculate average per capita savings. Calculate an average per capita amount of savings by taking a simple average of the values for each of the 3 performance years as determined in Step 1, including values of zero, if applicable. CMS will use the average per capita amount of savings to determine the ACO's eligibility for the prior savings adjustment as follows:

++ If the average per capita value is less than or equal to zero, the ACO will not be eligible for a prior savings adjustment. The ACO will receive the regional adjustment to its benchmark.

++ If the average per capita value is positive, the ACO will be eligible for a prior savings adjustment.

- *Step 3:* Apply a proration factor to the per capita savings calculated in Step 2 equal to the ratio of the average person years for the 3 performance years that immediately precede the start of the ACO's current agreement period (regardless of whether these 3 performance years fall in one or more prior agreement periods), and the average person years in benchmark years for the ACO's current agreement period, capped at 1. If the ACO was not reconciled for one or more of the 3 years preceding the start of the ACO's current agreement period, the person years from that year (or years) will be excluded from the averages in the numerator and the denominator of this ratio. For a new ACO that is identified as a re-entering ACO, the person years of the ACO in which the majority of the ACO participants of the re-entering ACO were participating will be used in the numerator of the calculation. This ratio will be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection, or changes to the beneficiary assignment methodology.

- *Step 4:* Determine final adjustment to benchmark. Compare the pro-rated positive average per capita savings from Step 3 with the ACO's regional adjustment, determined as specified in the regulation at § 425.656, expressed as a single per capita value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values.

++ If the regional adjustment, expressed as a single value, is negative or zero, calculate the sum of the regional adjustment value and the pro-rated positive average per capita savings value and determine the final adjustment as follows:

-- If the sum is positive, the ACO will receive a prior savings adjustment in place of the negative regional adjustment equal to the lesser of 50 percent of the sum of the pro-rated average per capita savings and the regional adjustment and 5 percent of national per capita FFS expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

--If this sum is negative, this will constitute the amount of the negative regional adjustment applied to the ACO's historical benchmark. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ If the regional adjustment, expressed as a single value, is positive, the ACO will receive an adjustment to the benchmark equal to the higher of the following:

-- The positive regional adjustment amount. The adjustment will be applied separately to the historical benchmark expenditures for each of the following populations of beneficiaries in accordance with § 425.656(c): ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

-- A prior savings adjustment equal to the lesser of 50 percent of the pro-rated positive average per capita savings value and 5 percent of national per capita FFS

expenditures for Parts A and B services in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3. The adjustment will be applied as a flat dollar amount to the historical benchmark expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

As we explained in the CY 2023 PFS final rule (87 FR 69900) in calculating an ACO's average per capita prior savings over the 3 performance years immediately preceding the start of its agreement period, we believe that a safeguard is needed to ensure that ACOs that achieved savings for a performance year that serves as a benchmark year for the current agreement period, but were ineligible to receive a shared savings payment due to noncompliance with Shared Savings Program requirements, are not subsequently eligible to have a portion of those savings included in their historical benchmark. Without such a safeguard, we would be rewarding an ACO, despite its noncompliance, through a higher benchmark in its subsequent agreement period. This would conflict with the sanction imposed on the ACO for its noncompliance during the performance year(s) of its prior agreement period. Accordingly, under the prior savings adjustment policy we finalized in the CY 2023 PFS final rule, if an ACO was ineligible to share in savings for any performance year in the 3 performance years immediately preceding the start of its agreement period due to noncompliance with Shared Savings Program requirements, we will set at zero the per capita amount of savings for the affected performance year(s) when calculating the prior savings adjustment.

There are a variety of reasons that could result in an ACO's ineligibility to receive a shared savings payment due to noncompliance. In accordance with §§ 425.605(c)(2), and 425.610(c)(2), an ACO does not qualify to receive shared savings for a performance year if it failed to meet the quality performance standard as specified under § 425.512 or otherwise did not maintain its eligibility to participate in the Shared Savings Program. Furthermore, an ACO will not receive any shared savings payments during the time it is under a corrective action plan (CAP) for avoidance of at-risk beneficiaries and is not eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at-risk beneficiaries) (refer to § 425.316(b)(2)(ii)(B) and (C)).

In the CY 2023 PFS rulemaking to establish the current prior savings adjustment, we did not describe how we would account for certain circumstances where there could be changes to the values used in calculating the prior savings adjustment. Such changes could occur as a result of changes in savings earned by ACOs in accordance with § 425.316(b)(2)(ii)(B) or (C) as a result of a compliance action to address avoidance of at-risk beneficiaries or issuance of a revised initial determination of financial performance under § 425.315. If CMS determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries and requires the ACO to submit a CAP, the ACO will not receive any shared savings payments during the time it is under the CAP (§ 425.316(b)(2)(ii)(B)), and it will not at any time be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (§ 425.316(b)(2)(ii)(C)). Upon completion of an ACO's CAP for avoidance of at-risk beneficiaries, CMS may release shared savings payments withheld from an ACO during the time it was under a CAP under § 425.316(b)(2)(ii)(B), so long as the shared savings are not attributable to the time that necessitated the CAP (that is, the time period during which the ACO avoided at-risk beneficiaries). Thus, depending on the timing of compliance actions undertaken by CMS, the amount of savings eligible for inclusion in the prior savings adjustment under § 425.658(b)(1), may change as a result of the compliance action. For instance, the total savings eligible for inclusion in the prior savings adjustment may increase after the completion of a CAP and release of shared savings payment withheld under § 425.316(b)(2)(ii)(B). Further, if an initial determination of financial performance was already made and shared savings payments distributed and then the ACO was found to have avoided at-risk beneficiaries and therefore ineligible to receive a shared savings payment for the performance year, CMS would recoup the shared savings for the time period during which the ACO avoided at-risk beneficiaries. This latter scenario would result in a decrease in the total amount of savings eligible for inclusion in the prior savings adjustment calculation.

Further, if CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, under § 425.315 CMS may reopen its prior determination and issue a revised initial determination: (1) at any time in the case of fraud or similar fault as defined in § 405.902; or (2) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause. If these situations—changes in the amount of shared savings for a prior performance year under § 425.316(b)(2)(ii)(B) or (C) as a result of a compliance action due to the avoidance of at-risk beneficiaries, or the issuance of a revised initial determination based on a reopening of ACO shared savings or shared losses under § 425.315—impact one of the 3 years prior to the start of the ACO's current agreement period, it is possible that the prior savings adjustment would no longer reflect the savings or losses achieved by the ACO during the applicable years. In the CY 2023 PFS rulemaking we did not adopt a mechanism to account for these changes in the prior savings adjustment, but rather focused on changes to the prior savings adjustment related to changes in an ACO's participant list, changes to the ACO's assignment methodology selection, or changes to beneficiary assignment methodology under the Shared Savings Program as a whole.

(2) Proposed Revisions

We are proposing refinements to the prior savings adjustment calculation methodology, specified in 42 CFR part 425, subpart G, that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, to account for circumstances where the amount of savings or losses for a performance year used in the prior savings adjustment calculation changes retroactively. Specifically, we are proposing to modify the list of circumstances for adjusting the historical benchmark in § 425.652(a)(9) to include two additional scenarios: a change in savings earned by an ACO in a benchmark year in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries, or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315. In these situations, the amount of savings or losses that an ACO may have generated in the 3 performance years prior to the

start of the current agreement period and that would have been eligible for inclusion in the calculation of the prior savings adjustment may change. The refinements we are proposing would allow for the prior savings adjustment to be recalculated and the historical benchmark to be adjusted to reflect the any change in the amount of savings earned or losses incurred by the ACO in the 3 performance years prior to its current agreement period that are eligible for inclusion in the calculation of the prior savings adjustment.

We are proposing to modify the process currently described in § 425.652(a)(9) for adjusting the historical benchmark. Currently, an ACO may receive an adjusted historical benchmark because of changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1),[193] or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E. We are proposing to modify § 425.652(a)(9) to indicate that an ACO would receive an adjusted historical benchmark for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. More specifically, an ACO would receive an adjusted benchmark for the following reasons: (1) a change in the amount of savings calculated for any of an ACO's three benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action taken to address avoidance of at-risk beneficiaries, or (2) CMS issues a revised initial determination under § 425.315 that impacts the amount of savings or losses calculated for one of the ACO's benchmark years. We note that a compliance action taken to address avoidance of at-risk beneficiaries may lead to a change in the amount of savings earned by an ACO for a previous performance year when CMS releases savings previously withheld under § 425.316(b)(2)(ii)(B) for a time period other than the time period during which the ACO avoided at-risk beneficiaries following completion of a CAP or CMS recoups shared savings previously disbursed to an ACO under § 425.316(b)(2)(ii)(C) for a time period during which the ACO is later determined to have avoided at-risk beneficiaries.

Only ACOs whose current benchmark includes a prior savings adjustment or whose benchmark would include an adjustment for prior savings following a change in the amount of savings earned for a previous performance year that is a benchmark year for the ACO's current agreement period would receive an adjusted benchmark under these proposed changes. Furthermore, we propose to modify the process currently described in § 425.652(a)(9) to indicate that if either of these two conditions occur after the ACO has already received its historical benchmark for the first performance year of its agreement period, an ACO could receive an adjusted historical benchmark for the first year of its agreement period.

We are also proposing to add a new paragraph (e) to § 425.658 to indicate that, when either of the two aforementioned scenarios occurs, the prior savings adjustment itself would be recalculated. Without this addition there is currently no mechanism for recalculating the prior savings adjustment to address changes in ACO's savings or losses for a performance year within an agreement period. Further, we are proposing that, absent any other triggers for receiving an adjusted benchmark, an ACO would only receive an adjusted historical benchmark due to a change in the ACO's savings or losses for a performance year under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) if the change would result in a change to the prior savings adjustment as determined under § 425.652(a)(8). In other words, the ACO would not receive an adjusted historical benchmark following recalculation of the prior savings adjustment if the recalculation of the prior savings adjustment would not result in a change to the historical benchmark.

We believe that, in order to issue adjusted benchmarks and complete financial reconciliation in a timely fashion, a need exists to establish a timing cutoff for when the determination to issue an adjusted historical benchmark for these two additional reasons would be made. Each of the two scenarios for which we are proposing to recalculate the prior savings adjustment may occur at any point during any performance year of the ACO's agreement period as well as after the end of that agreement period. We are proposing that for an adjusted benchmark due to the two conditions being considered to be used in financial reconciliation for a performance year, any determination that changes the amount of the ACO's savings or losses in any of the benchmark years under §§ 425.315 or 425.316(b)(2)(ii)(B) or (C) must be issued no later than the date of the initial determination of shared savings or shared losses through financial reconciliation for the relevant performance year under § 425.605(e) or § 425.610(h). Note that if we are aware of a potential change under § 425.316(b)(2)(ii)(B) or (C) in the savings earned in a benchmark year by an ACO eligible for the prior savings adjustment or an upcoming revised initial determination under § 425.315 that could impact the determination of the ACO's savings or losses for a benchmark year, we may delay the initial determination of shared savings or shared losses for the ACO for the relevant performance year beyond when initial determinations would otherwise be issued in order to assess whether the ACO should receive an adjusted historical benchmark. Under this framework, changes to savings or losses for a benchmark year that are finalized after notification to the ACO of the initial determination of shared savings or shared losses for a given performance year would be reflected in the adjusted benchmark applied to the subsequent performance year during the relevant agreement period but would not be retroactively applied to completed performance years in the agreement period.

We considered several alternatives to the timing of when we could incorporate new information about a change in savings earned by an ACO in accordance with § 425.316(b)(2)(ii)(B) or (C) or a revised initial determination under § 425.315 into the prior savings adjustment. The two primary alternatives we considered were: (1) requiring information about a change to the amount of savings calculated for a previous year in accordance with § 425.316(b)(2)(ii)(B) or (C) or a revised initial determination under § 425.315 to become available by December 31st of the year prior to the performance year; and (2) considering this information at any time it becomes available. An advantage of the former option of requiring information by December 31st is that it would allow us to issue the adjusted benchmark in March of the performance year, consistent with when adjusted benchmarks are otherwise issued to ACOs. A disadvantage of this approach is that it would provide less

[193] Refer to section III.G.7.a of this proposed rule for the proposal to revise the current reference to § 425.400(a)(4)(ii) in § 425.652(a)(9)(iv) to a reference to § 425.226(a)(1).

flexibility for when new information impacting savings or losses in the benchmark years could be applied to the benchmark used in financial reconciliation for a given performance year. An advantage of the latter approach of considering such information at any time that it becomes available is that an ACO could receive an adjusted benchmark and a revised initial determination of shared savings or shared losses even after receiving its initial determination for a performance year. However, a disadvantage of this approach is that it would generate significant operational complexities. If, for instance, information becomes available during performance year four of an ACO's agreement period that would potentially impact financial reconciliation results in the first 3 performance years of the agreement period, we would need to simultaneously issue adjusted benchmarks and revised initial determinations for several performance years. On balance, we believe it would be appropriate to consider new information that could impact the prior savings adjustment up to the point at which an ACO receives its initial determination for a particular performance year. We note that we are continuing to consider the complexities surrounding reopening initial determinations for multiple prior performance years throughout the program's benchmarking and financial reconciliation methodologies and may address this issue in future rulemaking.

We recognize that under § 425.658(b)(1)(iii), for a new ACO identified as re-entering ACO, the prior savings adjustment is based on the prior savings or losses of the ACO in which the majority of the ACO's ACO participants were participating. Accordingly, in the case of a re-entering ACO, we propose to consider whether this prior ACO is impacted by the following when determining whether to issue an adjusted benchmark: (1) a change in the amount of savings calculated for any of the ACO's benchmark years eligible for inclusion in the prior savings adjustment in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries; or (2) a revised initial determination issued under § 425.315 that impacts the determination of the ACO's savings or losses for one of the benchmark years. In this case, other aspects of this proposal would apply similarly, including the timing cutoff for issuing an adjusted benchmark and issuing an adjusted benchmark only if the change in savings or losses determined for the applicable benchmark year would result in a change to the prior savings adjustment as determined under § 425.652(a)(8).

Below are two examples that illustrate how an ACO could receive an adjusted historical benchmark that incorporates additional savings as a result of the changes we are proposing.

- *Example 1:* An ACO renews to begin a new agreement period on January 1, 2025 but is under a corrective action plan under § 425.316(b) for avoidance of at-risk beneficiaries during performance year 2023. In accordance with § 425.316(b)(2)(ii)(B) the ACO did not receive a shared savings payment for performance year 2024, which represents the third benchmark year of its new agreement period. Therefore, the ACO's prior savings adjustment for its new agreement period would be calculated by setting the gross savings and losses for the third benchmark year equal to 0 as described in § 425.658(b)(1)(ii). However, in November of 2026 the corrective action plan for avoidance of at-risk beneficiaries is closed and CMS determines that the ACO is eligible to receive payment for shared savings for performance year 2024. In this example, the ACO would have previously received notification of the initial determination of shared savings or shared losses for performance year 2025. Because the change in the status of the corrective action plan occurred after the ACO received its initial determination of shared savings and shared losses for performance year 2025, savings from the ACO's third benchmark year would be included in the calculation of the prior savings adjustment beginning with the benchmark used to determine financial performance for performance year 2026. That is, the ACO would receive an adjusted historical benchmark for performance year 2026 reflecting the recalculated prior savings adjustment, and financial reconciliation for performance year 2026 and subsequent performance years of the ACO's current agreement period would reflect that adjusted historical benchmark. However, financial reconciliation for performance year 2025 would not be reopened to reflect savings from the third benchmark year in the calculation of the prior savings adjustment because the corrective action plan was not lifted until after the ACO received its initial determination of shared savings or shared losses for that performance year.
- *Example 2:* An ACO begins a new agreement period on January 1, 2026, and receives its historical benchmark, which includes a prior savings adjustment. In February of 2027, information is identified that leads to a revised initial determination of shared savings and shared losses for benchmark year 2 of the ACO's new agreement period. Because the issue was identified in February of the second performance year of the new agreement period, which is prior to the ACO receiving an initial determination of its shared savings and shared losses for performance year 2026, the ACO would receive an adjusted historical benchmark for performance year 2026. Shared savings and shared losses calculations for performance year 2026 would reflect the recalculated prior savings adjustment included in this adjusted benchmark. All subsequent performance years in the agreement period would also reflect the recalculated prior savings adjustment.

In summary, we are proposing revisions to § 425.652(a)(9) to indicate that we would adjust the benchmark for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of the issuance of a revised initial determination under § 425.315. We are also proposing to add new paragraph (e) to § 425.658 to specify that the ACO's prior savings adjustment is recalculated for changes to the ACO's savings or losses for a performance year used in the prior savings adjustment calculation in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. Further, the new provision § 425.658(e) would also establish that for new re-entering ACOs, the prior savings adjustment will be recalculated for changes in savings or losses for a performance year used in the prior savings adjustment for the ACO in which a majority of the new ACO's ACO participants were previously participating.

We seek comment on this proposal to adjust the historical benchmark to reflect changes in savings or losses for a performance year that constitutes a benchmark year for an ACO's current agreement period. These changes would be applicable for agreement periods beginning on or after January 1, 2024.

e. Proposal To Update How Benchmarks Are Risk Adjusted

(1) Overview of Risk Adjustment Within Shared Savings Program Benchmark Calculations

When establishing, adjusting, and updating an ACO's historical benchmark, CMS makes certain adjustments to account for the severity and case mix of, and certain demographic factors for, the ACO's assigned beneficiary population and the assignable beneficiary population. We use prospective HCC risk scores and (as applicable) demographic risk scores to perform this risk adjustment.

To follow is a summary of the calculations in which we will account for the severity and case mix of the ACO's assigned beneficiary population or the assignable beneficiary population when establishing, adjusting, and updating the historical benchmark, for agreement periods beginning on January 1, 2024, and in subsequent years, including as proposed elsewhere in this proposed rule.

- We risk adjust benchmark year expenditures used to establish the historical benchmark for changes in severity and case mix using prospective HCC risk scores, in accordance with § 425.652(a)(3). In making this adjustment, we account for changes in severity and case mix in the ACO's assigned beneficiary population between the first and third benchmark years and between the second and third benchmark years.[194]
- We calculate the ACO's regional FFS expenditures using risk adjusted county-level FFS expenditures, which are determined in accordance with § 425.654(a)(4) by adjusting FFS expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores and by making separate expenditure calculations for populations of beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries). The ACO's risk adjusted regional FFS expenditures are utilized in determining the regional adjustment to the historical benchmark (in accordance with § 425.656), the regional component of the national-regional blended trend factor (in accordance with § 425.652(a)(5)), and the regional component of the three-way blended benchmark update factor (in accordance with § 425.652(b)(2)).
- We calculate the regional adjustment to the historical benchmark in accordance with § 425.656, including the following calculations to account for severity and case mix:

++ We adjust for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3 in accordance with § 425.656(b)(3).

++ In calculating the negative regional adjustment, we apply an offset factor based on the ACO's overall proportion of BY3 assigned beneficiaries who are dually eligible for Medicare and Medicaid (including dually eligible ESRD, disabled, and aged beneficiaries) and the ACO's weighted average prospective HCC risk score for BY3 taken across the four Medicare enrollment types, in accordance with § 425.656(c)(4).

- We adjust the ACO's historical benchmark to account for changes in severity and case mix in the ACO's assigned beneficiary population between BY3 and the performance year in accordance with §§ 425.652(a)(10), 425.605(a)(1) and (2) (BASIC track), and 425.610(a)(2) and (3) (ENHANCED track), at the time of financial reconciliation for a performance year. We use prospective HCC risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries between BY3 and the performance year, with positive adjustments subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year plus 3 percentage points (refer to §§ 425.605(a)(1)(ii) and 425.610(a)(2)(ii), and section III.G.4.b.(1) of this proposed rule).
- In calculating the regional component of the three-way blended update factor, we are proposing to cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor, as discussed in section III.G.4.b.(2) of this proposed rule and the proposed new provision at § 425.655.
- We adjust the flat dollar amounts of the ACPT component of the three-way blended update factor for each performance year, for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3, in accordance with § 425.660(b)(4).

(2) Background on Calculation of Prospective HCC Risk Scores Used To Risk Adjust Shared Savings Program Benchmark Calculations

(a) Historical Practices

We have detailed how CMS performs Shared Savings Program risk adjustment calculations in programmatic material, including publicly available specifications documents. See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 3.6, ''Risk Adjustment Policies''). While we have specified the details of these practices in guidance, we have not previously codified these practices in regulation.

More generally, CMS maintains the CMS–HCC risk adjustment models for the Medicare Advantage (MA) program. CMS maintains CMS–HCC risk adjustment models for populations of beneficiaries based on age, disability status, gender, institutional status, eligibility for Medicaid, and health status (see section 1853(a)(1)(C)(i) of the Act), including a separate MA risk adjustment model for the ESRD population, and a Part D risk adjustment model (known as the RxHCC model). Over time, CMS has implemented revised versions of the CMS–HCC risk adjustment models (also referred to generally as the ''CMS–HCC model''). Historically, transitions to a revised version of the CMS–HCC model have been gradually phased-in over time by blending the old risk adjustment model and the revised risk adjustment model. CMS specifies the CMS–HCC risk adjustment models applicable for a calendar year in the annual MA Rate Announcement (see sections 1853(a)(1)(C) and (b)(1) of the Act). Prior to doing so, CMS solicits comment on the CMS–HCC risk adjustment methodology (see section 1853(b)(2) of the Act). Using the specified model, or blend of models (if applicable), CMS calculates prospective HCC risk scores for all Medicare beneficiaries, including FFS beneficiaries. These prospective HCC risk scores are then used to set MA capitation rates and Part C and D payment policies for the applicable calendar year.

[194] See, for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (see section 3.6, ''Risk Adjustment Policies'').

To perform risk adjustment calculations for the Shared Savings Program, we calculate prospective HCC risk scores for Medicare FFS beneficiaries for the relevant benchmark year or performance year. In doing so, we use the CMS–HCC risk adjustment model(s) that are applicable for the particular calendar year corresponding to the benchmark or performance year to identify a Medicare FFS beneficiary's prospective HCC risk score for that benchmark or performance year. Prospective HCC risk scores used in financial calculations for the Shared Savings Program have the MA coding pattern adjustment of 5.90 percent removed, if applicable.[195] Additionally, all prospective HCC risk scores are renormalized by Medicare enrollment type based on a national assignable FFS population to ensure that the mean risk score among assignable beneficiaries is equal to one. Renormalization helps to ensure consistency in risk scores from year to year, given changes made to the underlying risk score models. All risk adjustment calculations for the Shared Savings Program, including risk score renormalization, are performed separately for each Medicare enrollment type for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, aged/non-dual eligible for Medicare and Medicaid.[196]

Under the Shared Savings Program, we calculate demographic only risk scores using a separate model than those used to calculate prospective HCC risk scores. For agreement periods beginning on January 1, 2024 and subsequent years, CMS will use demographic risk scores to determine the cap on risk score growth between BY3 and the performance year. Demographic risk scores consider only certain specified patient demographic factors, such as age, sex, Medicaid status, and the basis for Medicare entitlement (that is, age, disability, or ESRD), without incorporating diagnostic information. As such, demographic risk scores are not subject to changes in coding intensity or coding accuracy in the same way that prospective HCC risk scores are. We note that while the Shared Savings Program uses the same demographic factors as those used in MA, Shared Savings Program demographic factor coefficients are calibrated based on the entire Medicare FFS population instead of new Medicare enrollees as is used by MA.

Currently, when establishing, adjusting, and updating the benchmark, we account for changes in severity and case mix between benchmark years or between BY3 and the performance year by multiplying the expenditures for the applicable year by a quotient of two ACO-level renormalized risk scores, known as the risk ratio. For example, to risk adjust the expenditures for an ACO's assigned beneficiary population to account for changes in case mix and severity from the first benchmark year to the third, we multiply BY1 expenditures by a risk ratio equal to the mean renormalized risk score among the ACO's assigned beneficiaries in BY3 divided by the mean renormalized risk score among the ACO's assigned beneficiaries in BY1 for each Medicare enrollment type. For instance, a one percent rate of growth in renormalized risk scores between these benchmark years would be expressed by a risk ratio of 1.010. This ratio reflects growth in risk for the ACO's assigned beneficiary population relative to that of the national assignable population. Because the risk ratios used in benchmarking calculations may be determined using risk scores calculated from different underlying CMS–HCC risk adjustment models, depending on the CMS–HCC risk adjustment model(s) applicable to the corresponding benchmark or performance year, this approach allows for the possibility that differences in risk models between the benchmark years and the performance year could impact an ACO's financial performance.

Since the inception of the Shared Savings Program in 2012, there have been several CMS–HCC model changes. Several factors reduce the impact of using different risk adjustment models to calculate prospective HCC risk scores for benchmark and performance years when performing Shared Savings Program risk adjustment calculations. One factor is that the Shared Savings Program renormalizes prospective HCC risk scores by Medicare enrollment type, which ensures that the mean risk score for the national assignable FFS population for each enrollment type is equal to one. If a new CMS–HCC model leads to a shift in the mean of the distribution of prospective HCC risk scores for the national assignable FFS population for a particular Medicare enrollment type, then renormalizing the risk scores would counterbalance this effect. Because renormalization factors are calculated across the assignable beneficiary population for each enrollment type, any adverse or beneficial impact for an ACO from a change in CMS–HCC model would derive from the mean risk score for the ACO's assigned beneficiaries within a given enrollment type being impacted in a systematically different way than the mean for the national assignable population for that enrollment type.

A second factor is that risk scores are used in multiple ways that balance their effects when establishing, adjusting or updating a benchmark. Risk scores are used to adjust ACO expenditures and also to adjust regional expenditures used in calculating the regional adjustment to the benchmark and regional growth rates in benchmark calculations. Any impact of a new CMS–HCC model that could increase or decrease an ACO's risk scores used to establish, adjust or update a benchmark may differ directionally from the impact that risk scores for the assignable FFS population in an ACO's regional service area might have on risk-adjusted regional expenditure calculations. For example, if a new CMS–HCC model lowers the risk ratio between BY3 and the PY and therefore lowers the benchmark for an ACO, all else equal, then the new risk adjustment model may also lower the risk scores for the ACO's regional service area assignable beneficiary population, which would increase risk-adjusted regional expenditures.[197] This would put upward pressure on the benchmark by increasing the regional update factor. Any changes to the ACO's risk ratio may be thus reduced by changes to the ACO's regional update factor. This would reduce the impact of CMS–HCC model changes on ACO financial performance.

A third factor is that CMS–HCC model transitions have been gradually phased-in over time by blending the old risk adjustment model and the new risk adjustment model, thereby constraining the magnitude of any change in risk ratios resulting from differences in the risk adjustment models used to calculate prospective HCC risk scores.

[195] The MA risk adjustment models used for beneficiaries classified as ESRD for the Shared Savings Program (that is, beneficiaries in long-term dialysis or transplant status, no more than three months post-graft) do not currently employ a coding intensity adjustment, therefore no adjustment is currently removed from risk scores for beneficiaries in the ESRD enrollment type.

[196] A beneficiary's final risk score for each month is the risk score determined for that beneficiary based on the beneficiary's risk adjustment model status for that month. There are risk adjustment models for MA subpopulations (for example, community model versus institutional model versus new enrollee model for aged/non-dual eligible beneficiaries), and the risk scores used by the Shared Savings Program for beneficiaries in a Medicare enrollment type may be derived from more than one risk adjustment model.

[197] For each county and Medicare enrollment type (ESRD, disabled, aged/dual eligible, and aged/non-dual eligible) in the ACO's regional service area, CMS divides average per capita county-level FFS expenditures by the county average renormalized CMS–HCC risk score to obtain risk-adjusted county expenditures.

That is, as a result of this blending, the risk ratios used to adjust expenditures between BY3 and the PY may have some degree of overlap in underlying risk adjustment models used to calculate both the numerator and denominator of the risk ratios.

(b) Introduction of the 2024 CMS–HCC Risk Adjustment Model, Version 28

On March 31, 2023, CMS released the Announcement of CY 2024 MA Capitation Rates and Part C and Part D Payment Policies,[198] which finalized the transition to a revised CMS–HCC risk adjustment model. The revised 2024 CMS–HCC risk adjustment model, Version 28 (V28), has the same structure as the 2020 CMS–HCC risk adjustment model currently used for payment in that it has eight model segments as first implemented for payment for CY 2017 and condition count variables as first implemented for payment for CY 2020. It incorporates the following technical updates: (1) updated data years used for model calibration, (2) updated denominator year used in determining the average per capita predicted expenditures to create relative factors in the model, and (3) a clinical reclassification of the hierarchical condition categories (HCCs) using the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) codes. In addition, as part of the clinical reclassification, CMS conducted an assessment on conditions that are coded more frequently in MA relative to FFS. This assessment is consistent with Principle 10 of CMS's longstanding model principles, described in more detail initially in the December 2000 report titled, ''Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment (Final Report)'' (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/pope_2000_2.pdf*). As a result of this assessment, in addition to the technical updates, the revised model includes additional constraints and the removal of several HCCs in order to reduce the impact on risk score variation in coding between MA and FFS.[199]

For CY 2024, MA risk scores will be calculated as a blend of 67 percent of the risk scores calculated under the 2020 CMS–HCC risk adjustment model, Version 24 (V24), and 33 percent of the risk scores calculated with the 2024 CMS–HCC risk adjustment model (V28). CMS expects that for CY 2025, MA risk scores will be calculated using a blend of 33 percent of the risk scores calculated with V24 and 67 percent of the risk scores calculated with V28, and for CY 2026, 100 percent of risk scores will be calculated with V28.[200]

With the transition to the use of the V28 CMS–HCC model beginning in CY 2024 in MA, it is timely to revisit how we apply the CMS–HCC risk adjustment model(s) to calculate risk scores used in Shared Savings Program calculations. As summarized in the CY 2024 Rate Announcement, some commenters questioned if the updated MA risk adjustment model will affect lines of business outside of Medicare Advantage such as the ACO REACH Model and Medicare Shared Savings Program. In response to these comments, we explained that we were considering the implications of these changes to the CMS–HCC risk adjustment model for these initiatives.[201]

In section III.G.4.e.(3) of this proposed rule, we discuss our initial analysis of the impact of the V28 CMS–HCC model on Shared Savings Program calculations, including modeling of an alternative approach to calculating benchmark year risk scores. We propose a modified approach to making such calculations for agreement periods beginning on January 1, 2024, and in subsequent years, in section III.G.4.e.(4) of this proposed rule.

(3) Initial Analysis of the Impact of Risk Adjustment Model Changes on Shared Savings Program Calculations and Modeling of an Alternative Approach to Calculating Benchmark Year Risk Scores

To further evaluate the potential impact of the V28 CMS–HCC model transition on Shared Savings Program ACOs, we analyzed the following:

- Our current approach in which we apply the CMS–HCC risk adjustment model(s) applicable for a particular calendar year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the corresponding benchmark or performance year. This approach could lead to different CMS–HCC risk adjustment models being used to calculate prospective HCC risk scores for the benchmark years as compared to a particular performance year of the ACO's agreement period when there is a transition to a new CMS–HCC risk adjustment model between one or more benchmark years and the performance year.
- An alternative approach in which we would use the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period.[202] This approach ensures consistency between the CMS–HCC risk adjustment methodology used to calculate the prospective HCC risk scores for the benchmark years relative to a particular performance year.

To conduct this analysis, we calculated prospective HCC risk scores and risk ratios for CY 2018 (treated as BY3) and CY 2021 (treated as the PY) for all 275 ACOs that participated in both PY 2018 and PY 2021. Risk ratios between BY3 and the PY were calculated under the current approach, in which we used the V24 CMS–HCC model to calculate BY3 prospective HCC risk scores and the V28 CMS–HCC model to calculate PY prospective HCC risk scores, and under the alternative approach of calculating both BY and PY prospective HCC risk scores using V28.[203]

CMS performed this analysis to roughly estimate how V28 would have impacted payment to ACOs in PY 2021 using weighted average risk scores calculated across the three non-ESRD Medicare enrollment types (disabled, aged/dual eligible, aged/non-dual eligible). The analysis provides insight into the impact of a fully phased-in V28, which is expected to occur in PY 2026 (particularly for ACOs that would at that point have a BY3 prior to 2024). For the 275 ACOs in the sample, combined PY 2021 shared savings payments would have been about 11 percent lower than actual payments if V28 had been fully phased-in for the performance year,

[198] For more details, refer to Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (March 31, 2023) (herein CY 2024 Rate Announcement), available at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf.*

[199] See Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (February 1, 2023), available at *https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf.*

[200] See CY 2024 Rate Announcement, available at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf* at 3.

[201] *See id.* at 97.

[202] A similar approach was suggested by commenters in earlier rulemaking for the Shared Savings Program. See, for example, the December 2018 final rule (83 FR 68013), in which we summarize commenters' recommendation that CMS modify the current methodology to use the same CMS–HCC risk score model to calculate risk scores for both the benchmark years and the performance year.

[203] The V24 CMS–HCC model was not applicable to CY 2018 but was used in this analysis to calculate BY3 prospective HCC risk scores under the current approach in order to measure the impact of the transition from V24 to V28 on Shared Savings Program ACOs.

when using V24 to calculate BY3 prospective HCC risk scores (reflecting the current approach to applying CMS–HCC risk adjustment models). Alternatively, combined shared savings payments would have been about 2 percent higher than actual if V28 were used for BY3 calculations as well as for PY 2021 calculations (reflecting the alternative approach to applying CMS–HCC risk adjustment models).

Table 39 compares the estimated impact on PY 2021 shared savings of the current approach, and the alternative approach to calculating BY3 and PY prospective HCC risk scores.

TABLE 39: Estimated Impacts on PY 2021 Shared Savings of the V28 CMS-HCC Model under Current and Alternative Approaches to BY3 and PY Risk Score Calculation (Expressed as Percent of Benchmark)

	Current Approach BY3 V24, PY V28	Alternative Approach BY3 V28, PY V28	Current minus Alternative
Minimum	-6.6%	-1.6%	-6.7%
10th percentile	-1.4%	-0.4%	-1.1%
25th percentile	-0.4%	0.0%	-0.5%
Median	0.0%	0.0%	0.0%
Mean	-0.2%	0.1%	-0.2%
75th percentile	0.1%	0.2%	0.0%
90th percentile	0.9%	0.6%	0.5%
Maximum	2.3%	2.2%	2.2%

Estimated decreases in PY 2021 shared savings payments are more extreme at the tail of the distribution when using the current approach. Over 10 percent of ACOs showed more than 1.4 percent in reduced shared savings payments relative to benchmark under the modeling of the current approach, in which we used V24 to calculate BY3 prospective HCC risk scores and V28 to calculate PY prospective HCC risk scores. In contrast, about 3 percent of ACOs showed declines of such magnitude in shared savings payments relative to the benchmark using the alternative approach to calculating prospective HCC risk scores for BY3 and PY 2021 with the V28 CMS–HCC model. Compared to the alternative approach, the current approach is estimated to result in a reduction in shared savings of about 0.2 percent per ACO on average, relative to benchmark. These impacts would be smaller, potentially one-third of the magnitude, if the use of V24 in BY3 was compared to the blend of 33 percent V28 and 67 percent V24 for the PY (reflecting the blend applicable for CY 2024).

Table 40 compares the estimated impact on PY 2021 shared savings of the current approach, and the alternative approach to calculating BY3 and PY risk scores (expressed as percentage of benchmark), based on the following ACO characteristics: ACO average renormalized prospective HCC risk scores for aged/disabled beneficiaries, ACO participation in performance-based risk, and year of entry into the Shared Savings Program. We observed that the current approach would have the greatest adverse effect on ACOs with the highest average risk scores (calculated with the V24 CMS–HCC model), ACOs participating in two-sided models, and ACOs that have been in the Shared Savings Program longer. ACOs that would not have been harmed by the current approach had an average renormalized risk score for their non-ESRD populations roughly equal to 1.00. The 5 percent of ACOs in the modeling with the most adverse impact from the current approach had an average renormalized risk score for their non-ESRD populations of 1.22. For ACOs with the highest average risk scores, the modeling showed the current approach would have resulted in reduced shared savings of about 2 percent (relative to benchmark) per ACO, as compared to the alternative approach. The most adversely impacted ACOs in the modeling also were roughly 40 percent more likely to participate in a two-sided model and to have participated in the Shared Savings Program nearly 2 years longer than ACOs not harmed. The modeling demonstrates that the alternative approach would reduce the negative impact that the current approach shows for ACOs with high risk scores, with earlier entry dates into the Shared Savings Program, and with participation in a two-sided model.

TABLE 40: Estimated Impacts on PY 2021 Shared Savings of the V28 CMS-HCC Model under Current and Alternative Approaches to BY3 and PY Risk Score Calculation, Based on ACO Characteristics (Expressed as Percent of Benchmark)

	Current Approach BY3 V24, PY V28	Alternative Approach BY3 V28, PY V28	Current minus Alternative
Average HCC (Aged/Disabled)			
>1.20	-2.0%	0.0%	-2.1%
1.10 to 1.20	-0.5%	-0.1%	-0.4%
1.025 to 1.10	-0.4%	0.0%	-0.4%
0.975 to 1.025	-0.1%	0.1%	-0.2%
0.90 to 0.975	0.2%	0.2%	0.1%
<0.90	0.5%	0.2%	0.3%
PY21 Track/Level			
Two-sided Model	-0.5%	0.0%	-0.5%
One-sided Model	0.1%	0.1%	0.0%
Program Entry			
On/before 2013	-0.6%	0.1%	-0.7%
On/after 2014	-0.1%	0.1%	-0.1%

In the context of the transition to the V28 CMS–HCC model, the results of this analysis show that the current approach to calculating prospective HCC risk scores is expected to adversely impact ACO financial performance, particularly for ACOs that serve a high-risk beneficiary population, when compared to the stated alternative approach. The factors discussed in section III.G.4.e.(2) of this proposed rule—renormalizing risk scores to the national assignable FFS population, risk-adjusted regional expenditures providing a counterbalance to how risk ratios impact the benchmark, and the phased transition from V24 to V28 by means of a blended risk model—will reduce the impact of a risk adjustment model transition. However, these factors will be insufficient to prevent adverse effects on ACO financial performance due to the larger impact from the transition to V28 relative to prior CMS–HCC model transitions. The alternative policy under which CMS would apply the same CMS–HCC risk adjustment model used in the performance year to calculate prospective HCC risk scores for all benchmark years would strengthen risk adjustment in the Shared Savings Program and consistently apply the CMS–HCC model in the Shared Savings Program context as it is applied in MA.

(4) Proposed Revisions

The adoption of the alternative approach to calculating prospective HCC risk scores for the performance year and each benchmark year of an ACO's agreement period would allow us to more accurately measure the change in severity and case mix for an ACO's assigned beneficiary population or the assignable beneficiary population. Under such an approach, there would be no potential for distortion from using different CMS–HCC risk adjustment models in calculating prospective HCC risk scores for benchmark years and the performance year that could occur under the current policy. For this reason, we propose to modify our current use of the CMS–HCC risk adjustment model and adopt the alternative approach to calculating prospective HCC risk scores for a performance year and the relevant benchmark years for agreement periods beginning on January 1, 2024, and in subsequent years.

We propose to add a new section to our regulations at § 425.659, which would codify our existing framework for calculating risk scores used in Shared Savings Program benchmark calculations and adopt the alternative approach to calculating prospective HCC risk scores for a performance year and the relevant benchmark years discussed in this section of this proposed rule. We propose in paragraph (a) of § 425.659 to codify our current practice of accounting for differences in severity and case mix of the ACO's assigned beneficiaries and assignable beneficiaries (as defined under § 425.20) in calculations used in establishing, adjusting and updating the ACO's historical benchmark.

We propose to set forth in paragraph (b) of § 425.659 our approach to determining Medicare FFS beneficiary prospective HCC risk scores for Shared Savings Program benchmark and performance year calculations. In paragraph (b)(1) of § 425.659, we propose to codify our current policy under which CMS specifies the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores for Medicare FFS beneficiaries (as defined under § 425.20) for use in Shared Savings Program calculations. Additionally, we propose:

- To codify our current practice of calculating risk scores for Medicare FFS beneficiaries for a performance year, which provides that CMS uses the CMS–HCC risk adjustment methodology applicable for the corresponding calendar year.
- To codify our current practice for agreement periods beginning before January 1, 2024, of applying the CMS–HCC risk adjustment methodology for the calendar year corresponding to benchmark year in calculating risk scores for Medicare FFS beneficiaries

for each benchmark year of the agreement period.

- For agreement periods beginning on January 1, 2024, and in subsequent years, CMS would apply the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

We propose at § 425.659(b)(2) to codify our current practices for calculating prospective HCC risk scores for a benchmark or performance year. Specifically, in calculating prospective HCC risk scores, we would remove the MA coding intensity adjustment, if applicable. Further, we would renormalize prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on a national assignable FFS population for the relevant benchmark or performance year. We would calculate the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) in order to risk adjust benchmark calculations also performed by Medicare enrollment type.

We note that at this time we are not proposing to modify the current approach to calculating demographic risk scores under the Shared Savings Program, as described in section III.G.4.e.(1) of this proposed rule.

We also propose to adjust the benchmark to account for CMS–HCC risk adjustment model changes during the term of the agreement period to maintain uniformity between the calculation of prospective HCC risk scores for the performance year and each benchmark year. We propose to revise the list of circumstances for adjusting the historical benchmark for the second and each subsequent performance year during the term of the agreement period at § 425.652(a)(9) to include a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under proposed, new § 425.659. We further propose to add a new paragraph (a)(9)(vi) to § 425.652 to specify that we would redetermine factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with proposed § 425.659(b)(1).

We also propose a technical and conforming change to § 425.650(a), which generally describes the organization of the sections on the benchmarking methodology within subpart G of the Shared Savings Program regulations. In the description of the benchmarking methodology applicable for agreement periods beginning before January 1, 2024, we propose to update the list of referenced sections to include the proposed new § 425.659.

This proposed policy would address the concerns of ACOs and other interested parties regarding the transition to the V28 CMS–HCC model or other similar future changes to CMS–HCC risk adjustment methodology that could occur during the term of an ACO's agreement period. Under this proposal, both the numerator and denominator in the PY/BY3 risk ratio would be calculated using a consistent risk model, and any distributional impacts should, on average, be balanced. This would prevent distortion to historical benchmarks resulting from model changes. This conclusion is informed by the data analysis described in section III.G.4.e.(3) of this proposed rule, which shows that on average ACOs would have earned roughly 0.2 percent in additional PY 2021 shared savings payments relative to benchmark when both benchmark year and performance year prospective HCC risk scores are calculated under V28 compared to calculations under both V24 and V28.

Our analysis shows that ACOs with high risk scores would benefit from using the proposed approach to calculate BY and PY prospective HCC risk scores relative to the current policy. This proposal would therefore help the Shared Savings Program retain ACOs serving the highest risk beneficiaries. This is a priority for CMS as high risk beneficiaries may benefit the most from better care coordination and quality improvement activities, particularly by ACOs with above average duration of participation in the program. Similarly, the proposed approach would support potential participation from new ACOs that would consider whether risk adjustment calculations in the Shared Savings Program benchmarking methodology would be adequate for beneficiaries with the highest risk.

This proposal would not affect how prospective HCC risk scores are calculated for ACOs in agreement periods that began prior to January 1, 2024, consistent with our historical practice of incorporating changes to the benchmarking methodology only at the start of an ACO's agreement period. ACOs in an existing agreement period that includes performance year 2024, 2025 or 2026 may benefit from the factors discussed in section III.G.4.e.(2) of this proposed rule—renormalizing risk scores to the national assignable FFS population, risk-adjusted regional expenditures providing a counterbalance to how risk ratios impact the benchmark, and the phased transition from V24 to V28 by means of a blended risk model. These factors would diminish adverse effects of using the new CMS–HCC risk adjustment methodology in Shared Savings Program calculations.

If we finalize the proposed approach for agreement periods beginning on January 1, 2024, and in subsequent years, we note that an ACO in an existing agreement period may choose to terminate its participation agreement early in order to early renew under a new participation agreement to be under the revised approach. For instance, an ACO under an existing agreement period with the current methodology (with a 2022 or 2023 start date) could apply to early renew with the application cycle for the January 1, 2025 agreement period start date, which would occur during CY 2024. For an existing ACO that applied to early renew and enters a new agreement period beginning on January 1, 2024, the proposed policy, if finalized, would apply to the ACO's new agreement period. Any ACO that early renews would have its benchmark rebased at the start of the new agreement period.

The following examples, based on the first three years of a 5-year agreement period beginning on January 1, 2024, illustrate the applicability of the current approach to calculating BY and PY prospective HCC risk scores using different CMS–HCC risk adjustment model(s), as compared to the proposed approach to calculating both BY and PY prospective HCC risk scores using the same CMS–HCC risk adjustment model(s). Under the current policy an ACO beginning a new agreement period on January 1, 2024, would have its prospective HCC risk scores for BY1 (2021) calculated using a blend of 25 percent under the 2014 CMS–HCC model, Version 22 (V22), and 75 percent V24,[204] and for BY2 (2022) and BY3 (2023) calculated using V24.[205] [206] For

[204] For more details, refer to Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (April 6, 2020), available at *https://www.cms.gov/files/document/2021-announcement.pdf*.

[205] For more details, refer to Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA)

PY1 (2024), prospective HCC risk scores would be calculated using a blend of 67 percent V24 and 33 percent V28. For PY2 (2025), prospective HCC risk scores are expected to be calculated using a blend of 33 percent V24 and 67 percent V28. For PY3 (2026), prospective HCC risk scores are expected to be calculated using V28. Under the current methodology, the risk ratios used to risk adjust expenditures would have the numerator and denominator calculated using different underlying CMS–HCC risk adjustment models. Specifically, to risk adjust BY1 expenditures to BY3 when establishing or adjusting the ACO's historical benchmark, the risk ratio would include risk scores calculated under V24 (BY3) and a blend of 25 percent V22 and 75 percent V24 (BY1). To risk adjust BY3 expenditures to the performance year when updating the historical benchmark during financial reconciliation, risk ratios would include risk scores calculated under V24 (as applicable to BY3) and either a blend of V24 and V28 (for PY1 and as expected for PY2) or fully calculated with V28 (as expected for PY3).

Under the proposed approach, BY and PY prospective HCC risk scores would be calculated under the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the relevant performance year. For an ACO beginning a new agreement period on January 1, 2024, in PY1 (2024) all benchmark year and PY1 prospective HCC risk scores would be calculated using a blend of 67 percent V24 and 33 percent V28. In PY2 (2025), all benchmark year and PY2 prospective HCC risk scores are expected to be calculated using a blend of 33 percent V24 and 67 percent V28. In PY3 (2026), all benchmark year and performance year prospective HCC risk scores are expected to be calculated using V28. In the case of an ACO in an existing agreement period that early renews for a new agreement period beginning on January 1, 2025, the calculations described in this paragraph regarding the blend of V24 and V28 for 2025 and the fully phased-in V28 CMS–HCC model for 2026 would be expected to apply for the ACO's first and second performance years (respectively).

We seek comment on these proposals regarding the prospective HCC risk scores to be used in risk adjustment for purposes of benchmark calculations under the Shared Savings Program.

5. Proposed Modifications to Advance Investment Payments Policies

a. Overview

In the CY 2023 PFS final rule (87 FR 69782 through 69805), we finalized a new payment option for eligible Shared Savings Program ACOs entering agreement periods beginning on or after January 1, 2024, to receive advance shared savings payments. This payment option is referred to as advance investment payments (AIP) and the payments themselves are referred to as advance investment payments.

In that final rule, we explained that section 1899(i) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act so long as the Secretary determines that the other payment model would improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures (87 FR 69783 and 69784). In accordance with section 1899(i) of the Act, we determined that making advance investment payments to certain ACOs participating in the Shared Savings Program would improve the quality and efficiency of items and services furnished to Medicare beneficiaries by enhancing the accessibility of the Shared Savings Program (*Id.*).

We established standards for an ACO's receipt and use of advance investment payments within the Shared Savings Program regulations at § 425.630 and also specified requirements in connection with AIP in other sections within 42 CFR part 425. Such standards include: eligibility criteria to limit AIP to new, low revenue ACOs that are inexperienced with performance-based risk; application procedures and contents, including submission of a spend plan; policies governing use and management of payments; amount and frequency of advance investment payments, which are comprised of a one-time $250,000 upfront payment and up to 8 quarterly payments; the methodology for calculation of the quarterly payment amount based on the ACO's assigned population; termination of advance investment payments, as well as recoupment and recovery of advance investment payments; policies to monitor ACO eligibility for AIP; and ACO public reporting requirements regarding the use of advance investment payments.

Within this section of this proposed rule, we propose modifications to refine AIP policies to better prepare for initial implementation of AIP beginning with ACOs entering agreement periods on January 1, 2024. In summary, we are proposing to better support ACOs that are prepared to progress to performance-based risk by allowing ACOs to advance to two-sided model Levels within the BASIC track's glide path beginning in PY3 of the agreement period in which they receive advance investment payments (section III.G.5.b of this proposed rule). We are also proposing to recoup advance investment payments from shared savings for ACOs that wish to early renew to continue their participation in the Shared Savings Program (section III.G.5.c of this proposed rule). We propose to specify that CMS would terminate advance investment payments for future quarters to ACOs that elect to terminate their participation in the Shared Savings Program (section III.G.5.d. of this proposed rule). We propose to require ACOs to report spend plan updates and actual spend information to CMS in addition to publicly reporting such information (section III.G.5.e. of this proposed rule). We propose to codify that ACOs receiving advance investment payments may seek reconsideration review of all payment calculations (section III.G.5.f. of this proposed rule). If finalized, these policies would be effective beginning January 1, 2024.

b. Proposal To Modify AIP Eligibility Requirements To Allow ACOs To Advance to Performance-Based Risk During the 5-Year Agreement Period

(1) Background

The policies we finalized with the CY 2023 PFS final rule require an ACO to remain under a one-sided model for the duration of its agreement period in which it receives advance investment payments to remain compliant with AIP requirements. The ACO would otherwise face potential compliance action and may be required to repay all advance investment payments within 90 days of receiving written notification from CMS. This limits an ACO's ability to select participation options that include progression along the BASIC track's glide path to a performance-based two-sided risk model. This policy arises from the interaction of numerous standards.

First, an ACO is eligible to receive advance investment payments if CMS determines that all of the following criteria are met: (1) the ACO is not a

Capitation Rates and Part C and Part D Payment Policies (January 15, 2021), available at *https://www.cms.gov/files/document/2022-announcement.pdf.*

[206] For more details, refer to Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (April 4, 2022), available at *https://www.cms.gov/files/document/2023-announcement.pdf.*

renewing or a re-entering ACO; (2) the ACO has applied to participate in the Shared Savings Program under any level of the BASIC track's glide path and is eligible to participate in the Shared Savings Program; (3) the ACO is inexperienced with performance-based risk Medicare ACO initiatives; and (4) the ACO is a low revenue ACO (§ 425.630(b)). An eligible ACO will receive a one-time upfront payment of $250,000 and quarterly payments each quarter for the first 2 performance years of the ACO's 5-year agreement period, totaling no more than 8 quarterly payments (§ 425.630(f)).

Second, under § 425.630(h), CMS will terminate an ACO's advance investment payments in accordance with § 425.316(e) if the ACO is no longer inexperienced with performance-based risk Medicare ACO initiatives or is no longer a low revenue ACO. Section 425.316(e) specifies that if CMS determines during any performance year of the agreement period that an ACO receiving advance investment payments is experienced with performance-based risk Medicare ACO initiatives or is a high revenue ACO, and the ACO remains experienced with performance-based risk Medicare ACO initiatives or a high revenue ACO after a deadline specified by CMS pursuant to compliance action, the ACO must repay all advance investment payments it received.

An eligible ACO that joins the Shared Savings Program in Level A of the BASIC track and opts to receive advance investment payments will be eligible for all 8 quarterly payments to be paid over PY1 and PY2, so long as the ACO remains in Level A (or progresses to Level B) in PY2 and remains inexperienced with performance-based risk Medicare ACO initiatives and a low revenue ACO. An ACO that joins the Shared Savings Program at Levels B through E of the BASIC track, however, will not be eligible to receive all 8 quarters of advance investment payments because current program regulations require that an ACO remain inexperienced with performance-based risk Medicare ACO initiatives while receiving advance investment payments (§ 425.630(h)(2)). More specifically, if an ACO receiving advance investment payments elects to participate at Level B of the BASIC track in PY1 progresses along the glide path to Level C for PY2, CMS would determine that the ACO is experienced with performance-based risk in PY2 and the ACO would no longer be eligible to receive advance investment payments during PY2.

In the CY 2023 final rule (87 FR 69787), we stated that advance investment payments were intended to assist smaller, community-based providers in forming high-performing ACO networks by providing much-needed startup capital that can be used to attract and maintain staffing, purchase healthcare delivery infrastructure and IT systems, and develop and implement a strategy to address the health needs of underserved communities. It is for this reason we restricted AIP eligibility to those ACOs that are inexperienced with performance-based risk. ACOs that are experienced with performance-based risk generally would not need advance investment payments to successfully participate in the Shared Savings Program as they have previously participated in the Shared Savings Program or certain Innovation Center models or CMS programs in which the ACO accepted risk for shared losses. In this proposed rule, we propose to modify program regulations to permit an ACO to progress to two-sided risk along the BASIC track's glide path within the agreement period while the ACO continues to benefit from advance investment payments.

(2) Proposed Revisions

We propose to modify AIP eligibility requirements to allow an ACO receiving advance investment payments to transition to two-sided risk within its 5-year agreement period under the BASIC track's glide path. Specifically, we propose to modify § 425.630(b)(2) and (3) to allow an eligible ACO receiving advance investment payments to advance to performance-based risk (by advancing from Level A or B to Level C, D, or E of the BASIC track's glide path) beginning in PY3 of the ACO's agreement period. We also propose to modify § 425.316(e)(2) to specify that CMS would cease payment of advance investment payments if CMS determines that an ACO approved for AIP became experienced with performance-based risk Medicare ACO initiatives during the first or second performance year of its agreement period or became a high revenue ACO during any performance year of the agreement period in which it received advance investment payments. Pursuant to § 425.316(e)(2)(ii), CMS may take compliance action against such ACOs. We also propose to modify § 425.316(e)(2)(i) to specify that CMS will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

Under the proposed approach, ACOs may choose to move into a two-sided risk participation option within the Shared Savings Program's BASIC track beginning in PY3 (and in subsequent performance years). These ACOs would still be required to repay advance investment payments through earned shared savings over the remaining performance years of its agreement period as prescribed in § 425.630(g). We propose that this policy would be effective January 1, 2024. Under this proposal, an ACO could not use advance investment payments to fund repayment mechanisms or repay shared losses. This limitation also reduces the risk that ACOs stretch themselves beyond their financial capacity while receiving advance investment payments by taking on large amounts of risk. Unlike other ACOs, ACOs receiving advance investment payments will have the additional financial obligation of repaying the advance investment payments if they misjudge their appetite for risk and leave the program mid performance period after incurring shared losses. These policies are intended to align with our goal to support the creation of new ACOs that need time and resource assistance to develop the infrastructure to operate an ACO that effectively manages patient care and lowers costs.

After 2 years of participation, new ACOs may have sufficient experience to be capable of taking on the smaller amounts of downside risk available in levels C–E of the BASIC track. Given that the option to receive advance investment payments was designed for ACOs that are new to the Shared Savings Program, low revenue, and inexperienced with risk, it does not align with broader program goals to permit ACOs of such size or capitalization to take on the high levels of downside risk in the ENHANCED track during their first agreement period in the Shared Savings Program. As proposed, these modifications balance the risk of a new ACO taking on too much risk too quickly while allowing them to take on moderate risk as they develop more experience with the program.

Specifically, we propose to amend the eligibility criteria specified in § 425.630(b) as follows. We propose to revise the eligibility criterion at § 425.630(b)(2) to remove language stating that the ACO has applied to participate in the Shared Savings Program ''under any level of the BASIC track's glide path''; the revised provision would simply state that ''CMS has determined that the ACO is eligible to participate in the Shared Savings

Program.'' Further, we propose to amend the criterion in § 425.630(b)(3) to specify that the ACO must be inexperienced with performance-based risk Medicare ACO initiatives during its first 2 performance years but may participate in Levels of the BASIC track that would make them experienced with performance-based risk Medicare ACO initiatives starting with the third year of its first agreement period. Specifically, we propose to specify in revisions to § 425.630(b)(3), that the ACO may participate in the Levels of the BASIC track's glide path as follows during the agreement period in which the ACO receives advance investment payments:

- For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.
- For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)) or Level B.
- For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)), or Levels B through E.

To illustrate the proposed policy, consider an ACO entering an agreement period beginning on January 1, 2024, that applies for and is determined to be eligible to receive advance investment payments. The ACO must participate in Level A for PY1. In PY2, the ACO may remain under Level A for all subsequent years of the agreement period in accordance with § 425.600(a)(4)(i)(C)(*3*) or may move to Level B. The ACO would receive advance investment payments for PY1 and PY2, receiving the one-time payment of $250,000 and the 8 quarterly payments. If the ACO remained at Level A for PY2, it could then transition to a higher level of risk and potential reward within the glide path for PY3 (that is, Levels B, C, D, or E) in accordance with § 425.600(a)(4)(i)(C)(*3*)(*iii*). If the ACO participated in Level B for PY2, it could automatically progress for PY3 to Level C (in accordance with § 425.600(a)(4)(i)(C)(2)) or elect to transition to Level D (in accordance with § 425.600(a)(4)(i)(C)(2)(i) and § 425.226(a)(2)(i)) or Level E (in accordance with § 425.600(h)(2)(i) and § 425.226(a)(2)(i)) beginning with PY3.

Under this proposed modification, CMS would continue to recoup from future shared savings. In contrast to what is required under existing § 425.316(e)(3), the ACO would not be immediately obligated to repay all advance investment payments it received by virtue of its transition to a two-sided model in its third performance year or any subsequent performance year. We note that under our proposal if an ACO opts to progress to a two-sided risk model (BASIC track's glide path Levels C through Level E) in PY2, CMS would terminate the ACO's advance investment payments, the ACO may be subject to compliance actions specified in §§ 425.216 and 425.218, and CMS may seek repayment of advance investment payments as set forth at § 425.316(e).

We seek comment on our proposals to amend AIP policies and require that all AIP ACOs be inexperienced with performance-based risk Medicare ACO initiatives while the ACO receives advance investment payments—that is, during PY1 and PY2 of the agreement period—and to allow ACOs to progress to performance-based risk under the BASIC track's glide path beginning with PY3 of the same agreement period.

c. Proposal To Modify AIP Recoupment and Recovery Policies for Early Renewing ACOs

(1) Background

In the CY 2023 PFS final rule (87 FR 69803 through 69805), CMS finalized program policies regarding recoupment and recovery of advance investment payments. In accordance with § 425.630(g)(4), if an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

Paragraph (2) of the definition of ''renewing ACO'' at § 425.20 includes an ACO that continues its participation in the Shared Savings Program for a consecutive agreement period, without a break in participation, because it is an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program. In prior rulemaking (see, for example, 83 FR 67885 through 67890), we have referred to this provision as allowing for an ''early renewal'' option. In developing the AIP policies in the PFS rulemaking for CY 2023, we did not address the potential interactions between the policy on recovery of advance investment payments specified in § 425.630(g) and a voluntary termination of the participation agreement by an ACO that is seeking to early renew.

(2) Proposed Revisions

We propose to amend § 425.630(g)(4) to create a limited exception to CMS's policy of recovering advance investment payments from an ACO that voluntarily terminates its participation agreement for the agreement period during which it received advance investment payments. Under this proposal, we would not seek to collect all advance investment payments received from an ACO in accordance with § 425.630(g)(4) if the ACO voluntarily terminates its participation agreement at the end of PY2 or later during the agreement period in which it received advance investment payments, provided that the ACO immediately enters into a new participation agreement with CMS under any level of the BASIC track's glide path or the ENHANCED track. Rather, we would carry forward any remaining balance of advance investment payments owed by the early renewing ACO into the ACO's new agreement period.

We propose to allow an ACO approved for AIP to early renew its participation agreement before the expiration of its current agreement, as long as the ACO terminates its current participation agreement effective on or after December 31 of the ACO's second performance year. By requiring the ACO to maintain its current agreement period for the first 2 years, the ACO will receive all of its advance investment payments prior to renewing its participation agreement. We further propose that in such circumstances, the early renewing ACO must continue to repay the advance investment payments through shared savings earned in the subsequent agreement period. If an ACO early renews prior to PY3, it will no longer comply with the eligibility requirements for receiving payments in § 425.630(b)(1) and may be subject to compliance actions under §§ 425.216 and 425.218.

Section 425.630(e)(3) specifies that an ACO may spend an advance investment payment over its entire agreement period and must repay to CMS any unspent funds remaining at the end of the ACO's agreement period. We propose to amend § 425.630(e)(3) to permit an early renewing ACO to spend advance investment payments in its second agreement period so long as the advance investment payments are spent within 5 performance years of when it began to receive advance investment payments. If the ACO does not spend all of the advance investment payments received by the end of the fifth performance year, the ACO must repay any unspent funds to CMS. The

duration of spending advance investment payments was discussed in the CY 2023 PFS final rule (87 FR 69801).

We believe these policy proposals would be most relevant to an ACO that is receiving advance investment payments and seeks to early renew to enter a new participation agreement to participate under modified Shared Savings Program policies that are not applicable to the ACO's current agreement period. For such an ACO, any remaining balance of advance investment payments owed would continue to be recouped from any shared savings the ACO earns in its new agreement period. Further, such an ACO would continue its participation in the Shared Savings Program without a lapse in participation and would be required to continue to adhere to all AIP requirements. We believe continued program participation aligns with our goals to improve the quality and efficiency of care. These policies provide ACOs the flexibility to participate in the Shared Savings Program in a manner that may work best for their structure and patient population without having to choose between immediately paying back the advance investment payment funds they received and being able to enter a new agreement with the Shared Savings Program. Some policy changes are applicable to new agreement periods, and we believe ACOs approved for AIP should have the opportunity to enter a new agreement to experience those changes. This proposed modification, if finalized, would be effective January 1, 2024.

We seek comment on the proposed changes to § 425.630(e)(3) and § 425.630(g)(4).

d. Proposal To Amend Termination Policies To Allow CMS To Cease Distribution of Advance Investment Payments Following an ACO's Notification of Voluntary Termination

(1) Background

In the CY 2023 PFS final rule (87 FR 69803), we finalized policies for termination of advance investment payments at § 425.630(h). Section 425.630(h)(1) specifies that CMS may terminate an ACO's advance investment payments if the ACO fails to comply with the requirements of § 425.630 or meets any of the grounds for ACO termination set forth in § 425.218(b). However, we did not address the termination of advance investment payments if an ACO voluntarily terminates its participation agreement in accordance with § 425.220(a). This created ambiguity regarding whether CMS would continue to make quarterly advance investment payments to an ACO that voluntarily terminates its participation agreement in accordance with § 425.220(a) and does not immediately enter a new agreement period. We are concerned that the continued payment of advance investment payments in such a case would not serve the purpose for which CMS is making such payments and would create unnecessary program integrity risks for the Shared Savings Program. In such a case, CMS would be knowingly paying funds to an ACO that will need to be repaid upon termination.

(2) Proposed Revisions

We propose to permit CMS to terminate advance investment payments for future quarters to an ACO that has provided CMS with notice of termination in accordance with § 425.220(a) if the ACO will not immediately enter a new agreement period. This avoids distributing advance investment payments to an ACO from which CMS would subsequently need to recover such payments. Specifically, we propose to add § 425.630(h)(1)(iii), which allows CMS to terminate an ACO's advance investment payments when the ACO voluntarily terminates its participation agreement in accordance with § 425.220(a). We are also proposing conforming changes to the punctuation of the list of factors in paragraphs (h)(1)(i) and (ii) of § 425.630. If finalized, these proposed changes would be effective January 1, 2024.

In summary, if finalized, CMS will cease paying advance investment payments to an ACO that voluntarily terminates its participation in the Shared Savings Program if the ACO will not immediately enter a new agreement period. In accordance with § 425.630(g)(4), the ACO would still be obligated to repay all advance investment payments within the 90-days after receiving notice of the amount due to CMS. We seek comment on this proposal.

e. Proposal To Require ACOs To Report to CMS Spend Plan Updates and Use of Advance Investment Payments

In the CY 2023 PFS final rule (87 FR 69786 through 69788), CMS finalized program policies to require ACOs that receive advance investment payments to submit a spend plan to CMS as a part of their Shared Savings Program application (§ 425.630(d)(1)). In accordance with § 425.630(d)(3), CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the spend plan requirements specified at § 425.630(d)(2) and the requirements for use and management of advance investment payments at § 425.630(e).

In the CY 2023 PFS final rule (87 FR 69801 and 69802), we also finalized requirements at § 425.308(b)(8) that an ACO receiving advance investment payments must publicly report information, updated annually, about the ACO's use of advance investment payments for each performance year, including the following:

- The ACO's spend plan.
- The total amount of any advance investment payments received from CMS.
- An itemization of how advance investment payments were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan submitted under § 425.630(d), and such other information as may be specified by CMS.

These provisions do not require an ACO to submit this same information to CMS. To support CMS's ability to monitor AIP efficiently, we propose that an ACO must report to CMS the same information about its use of advance investment payments that it is required to publicly report under § 425.308(b)(8).

To ensure that § 425.630 sets forth the complete requirements applicable to an ACO's obligation to report information on its receipt and use of advance investment payments, we propose to add a new provision at § 425.630(i) specifying that an ACO must (1) publicly report information about the ACO's use of advance investment payments for each performance year in accordance with § 425.308(b)(8); and (2) in a form and manner and by a deadline specified by CMS, report to CMS the same information it is required to publicly report in accordance with § 425.308(b)(8).

We believe that these proposed changes would help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving advance investment payments and thereby support CMS's monitoring and analysis of the use of advance investment payments. CMS believes that these proposed changes will impose little to no administrative burden on participating ACOs, which are already required to publicly report this information by § 425.308(b)(8). Further, CMS expects to use the submitted data as the template that ACOs can use to populate their public reporting web page early in each performance year to minimize administrative burden for ACOs.

If finalized, these proposed changes would be effective January 1, 2024. We seek comment on these proposals.

f. Proposal To Permit Reconsideration Review of Quarterly Payment Calculations

(1) Background

In the CY 2023 PFS final rule (87 FR 69795 and 69796), we specified that an ACO can request a reconsideration review if CMS does not make an advance investment payment to the ACO pursuant to subpart I of part 425 (§ 425.630(f)). However, we did not specify that an ACO could request reconsideration of the advance investment payment amount received.

(2) Proposed Revisions

We propose to permit an ACO to request a reconsideration review for all advance investment payment quarterly payment calculations, not just instances where no payments are distributed. We propose to revise § 425.630(f) to provide that CMS would notify in writing each ACO of its determination of the amount of advance investment payment it will receive and that such notice would inform the ACO of its right to request reconsideration review in accordance with the procedures specified under subpart I of the regulations. We seek comment on this proposal.

6. Shared Savings Program Eligibility Requirements

a. Overview

We are proposing two modifications to the Shared Savings Program eligibility requirements that, if finalized, would be implemented on January 1, 2024. Specifically, we propose the following, which are discussed in more detail in sections (b) and (c) below:

- Remove the option for ACOs to request an exception to the shared governance requirement that 75 percent control of an ACO's governing body must be held by ACO participants.
- Codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was or will be included on a participant list used in financial reconciliation for a performance year under performance-based risk during the 5 most recent performance years.

b. Shared Governance Requirement

(1) Background

In the November 2011 final rule (76 FR 67819), we finalized policies that require an ACO to establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO, and we codified the governing body policies at § 425.106. Specifically, § 425.106(c)(3) mandates that at least 75 percent control of an ACO's governing body must be held by ACO participants. An ACO's governing body is responsible for providing ACO leadership, strategic direction, and oversight for operational management towards meeting the goals of the ACO, including better care, healthy communities, and reduced spending. This responsibility incorporates not only the delivery of improved healthcare, but also the promotion of evidence-based healthcare practices, improved engagement of patients and caregivers, reporting on quality and cost, provision of high-quality care to beneficiaries, and the distribution of shared savings, among other functions. In the November 2011 final rule (76 FR 67819), we indicated our belief that this requirement allowed for Medicare-enrolled entities that directly provide health care services to beneficiaries to drive decision-making, while recognizing that partnerships with non-Medicare enrolled entities outside this 75 percent composition allow these participants access to capital and infrastructure needed for an ACO. This physician-driven leadership is balanced by the remaining percentage of the governing body that is made up of patient advocates, accounting, legal and other professionals that support administrative duties and other functions of the ACO.

We affirmed in the November 2011 final rule (76 FR 67820) our belief that the 75 percent participant control requirement is necessary to ensure that ACOs are provider-driven, innovative in care delivery and strike an appropriate balance to incentivize and empower ACO participants to be accountable for the success of the ACO's operations and improve the health outcomes of their beneficiaries. Previously, commenters expressed concern that the 75 percent participant control threshold is overly prescriptive and may hinder operations, conflict with IRS and State tax laws, and restrict access to capital for the ACO. ACOs requested flexibility to develop their own governing body composition to meet the unique leadership needs of the ACO. In response to these comments, CMS granted an exception process for an ACO that wishes to structure its governing body in a manner that does not meet the 75 percent participant control threshold as required under § 425.106(c)(3). Under the exception process defined at § 425.106(c)(5), an ACO must describe why it seeks to differ from the 75 percent participant control threshold and how the ACO will involve ACO participants in innovative ways in ACO governance. If the exception is granted by CMS, an ACO can form a governing body with less than 75 percent participant control.

In the December 2014 Medicare Shared Savings Program proposed rule (79 FR 72776) we proposed to revise § 425.106(c)(5) to remove the flexibility for ACOs to deviate from the requirement that at least 75 percent control of an ACO's governing body must be held by ACO participants. We stated that, through program implementation, we learned that ACO applicants do not have difficulty meeting the requirements under § 425.106(c)(3) that ACO participants maintain 75 percent control of the governing body. We also noted that since CY 2012, we had not denied participation to any ACO applicants solely based on failure to comply with this requirement and no exceptions have been granted by CMS under § 425.106(c)(5). Furthermore, we affirmed the 75 percent participant control requirement to be ''necessary and protective of the ACO participant's interests'' and thus, that there was no reason to continue to offer an exception to the rule.

During the public comment period for the December 2014 Medicare Shared Savings Program proposed rule, several commenters advocated for retaining the flexibility offered at § 425.106(c)(5), stating that an ACO may elect to utilize the exception in the future. In our response, we noted that our program experience thus far had not suggested that commenters' concerns that laws concerning the composition of tax-exempt or State-licensed entities would interfere with their ability to meet the 75 percent participant control threshold would impact their compliance with this requirement. However, since implementation of the requirement remained in the early stages and we had limited applicability with ACOs in two-sided risk tracks, we declined to finalize the proposal in the June 2015 final rule (80 FR 32719) and elected to retain the flexibility at § 425.106(c)(5). In the final rule, we noted that we anticipated granting such exceptions only in limited circumstances (that is, an ACO being unable to meet the 75 percent participant control requirement because it conflicts with other laws) and might revisit this issue in future rulemaking.

(2) Proposed Revisions

We continue to believe that ACO participants should drive ACO

leadership to move toward improved quality of care and patient outcomes, and that this is a key component of ACO success and ability to earn shared savings. The 75 percent participant control threshold is critical to ensuring that governing bodies are participant-led and best positioned to meet program goals, while allowing for partnership with non-Medicare enrolled entities to provide needed capital and infrastructure for ACO formation and administration.

Over the years, a few ACOs have requested an exception to form a governing body with less than 75 percent participant control. CMS discussed the exemption requests with the interested ACOs and ultimately the ACOs made adjustments to comply with the 75 percent participant control requirement. To date, CMS has not granted an ACO an exception to this requirement, despite the flexibility provided in current regulation. Accordingly, we believe that there is no reason to continue to offer an exception to the requirement, as ACOs have demonstrated that they can appropriately meet the 75 percent participant control requirement without utilizing this flexibility since its establishment in the November 2011 final rule. Thus, we propose to remove the option under § 425.106(c)(5) for ACOs to request an exception to the requirement specified in § 425.106(c)(3) that 75 percent control of the ACO's governing body must be held by ACO participants. Additionally, we propose a corresponding revision to § 425.204(c)(3) to remove the option for ACOs to request an exception to the 75 percent control requirement under § 425.106(c)(3) as part of their Shared Savings Program applications.

We are seeking public comments on the appropriateness of our proposed policy refinement and elimination of the exception process. If finalized, our proposed modification to § 425.106(c) would make no changes to paragraphs (c)(2), (3) and (4). CMS would amend § 425.106(c)(5) to remove reference to paragraph (c)(3) and the procedure for submitting a request for an exception to the 75 percent requirement. Specifically, the revised regulation text would state: ''In cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.'' Additionally, CMS would amend § 425.204(c)(3) to remove references to § 425.106(c)(3) and the procedure for submitting a request for an exception to the 75 percent requirement. Specifically, the revised regulation text would state: ''If an ACO requests an exception to the governing body requirement in § 425.106(c)(2), the ACO must describe—(i) Why it seeks to differ from the requirement; and (ii) How the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.'' If finalized, this policy would be effective beginning January 1, 2024.

c. Identifying ACOs Experienced With Risk Based on TINs' Prior Participation

(1) Background

In the December 2018 final rule, we added a new paragraph (d) under § 425.600 to set forth the participation options for ACOs that are experienced or inexperienced with ''performance-based risk Medicare ACO initiatives'' (which is defined at § 425.20 to include certain Innovation Center ACO models as well as two-sided risk tracks of the Shared Savings Program). We also finalized the definitions of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' (83 FR 68062). These definitions classify ACOs by experience level based on the percentage of ACO participant TINs that participated in performance-based risk Medicare ACO initiatives during a 5-year lookback period. However, current regulation text does not specify how CMS determines whether an ACO participant TIN has ''participated'' in a performance-based risk Medicare ACO initiative. To improve clarity of the regulations, we propose to codify our existing program policy under which an ACO participant TIN is considered to have participated in a performance-based risk Medicare ACO initiative if it was or will be included in financial reconciliation for a performance year under such initiative during any of the 5 most recent performance years.

Under the December 2018 final rule, an ACO is ''inexperienced with performance-based risk Medicare ACO initiatives'' (and therefore eligible to enter an agreement period under the BASIC track's glide path), if less than 40 percent of its ACO participants has participated in a performance-based risk Medicare ACO initiative in ''each'' of the 5 most recent performance years prior to its Shared Savings Program agreement start date, and the ACO legal entity has not participated in any performance-based risk Medicare ACO initiative (83 FR 67895). Similarly, an ACO is ''experienced with performance-based risk Medicare ACO initiatives'' if 40 percent or more of its ACO participants has participated in a performance-based risk Medicare ACO initiative in ''any'' of the 5 most recent performance years prior to its Shared Savings Program agreement start date (83 FR 67895). Thus, if 40 percent or more of the entities on an ACO participant list participated in a performance-based risk Medicare ACO initiative in a single performance year within the 5 most recent performance years, we would determine that the ACO meets the definition of ''experienced with performance-based risk Medicare ACO initiatives.'' Conversely, we would determine that an ACO satisfies the definition of ''inexperienced with performance-based risk Medicare ACO initiatives'' only if it is below the 40 percent threshold in all of the 5 most recent performance years prior to the ACO's agreement start date. In other words, an ACO is inexperienced with performance-based risk Medicare ACO initiatives as long as it does not meet the definition of ''experienced with performance-based risk Medicare ACO initiatives'' in any of the five most recent performance years prior to the ACO's agreement start date. We chose to use a 5-year lookback period for determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives for a number of reasons, including that it could reduce the incentive for organizations to wait out the period in an effort to establish a new legal entity with the same or very similar composition of ACO participants for purposes of gaming program policies.

We recognize that some ACOs or TINs in performance-based risk Medicare ACO initiatives participate for only part of a performance year, but our current regulation text does not specify the duration of participation required for CMS to determine that an ACO participant TIN has participated in a performance-based risk Medicare ACO initiative.

(2) Proposed Revisions

We propose to codify the current operational approach for determining whether an ACO participant has participated in a performance-based risk Medicare ACO initiative. Under our current operational approach, an ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if its TIN was or will be used to calculate financial reconciliation for the entity participating in such ACO initiative (''Initiative ACO''). In general, if an ACO

participant was included on an Initiative ACO's participant list for a performance year during the 5 most recent performance years before the ACO's agreement start date, and the Initiative ACO is, or will be, financially reconciled for that performance year, the ACO participant will be considered to have participated in the Initiative ACO. This will generally be true regardless of whether the entity leaves the Initiative ACO mid-performance year, because its claims experience would still be used in the Initiative ACO's alignment and financial reconciliation for that performance year. If the ACO participant was included on an Initiative ACO's participant list for a performance year during the lookback period, but the ACO voluntarily terminates before the deadline for reconciliation or is otherwise not eligible for reconciliation, the ACO participant will not be considered to have experience with risk because its claims experience would not be used for financial reconciliation.

Except for determinations made regarding AIP ACOs for purposes of § 425.316(e)(2), we determine whether an ACO is experienced with performance-based risk Medicare ACO initiatives prior to the start of an ACO's agreement start date. At the time we make these determinations, the ACO may be in the middle of a PY for which reconciliation has not yet occurred. Nevertheless, we believe that at the time we make these determinations, we have the information necessary to determine whether an ACO or ACO participant TIN will be included in financial reconciliation for a PY in the relevant Medicare ACO initiative because this issue is addressed in the terms of each Medicare ACO initiative. For example, as outlined in § 425.221(b)(2)(ii)(A), if an ACO in a two-sided model terminates from the Shared Savings Program after June 30th of a PY, they will be held responsible for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. Any ACO participant TIN that was included on the participant list for that performance year will have been included in beneficiary alignment and their claims experience used to calculate the benchmark and performance year expenditures. For other Medicare ACO initiatives, the terms of the participation agreement specify when the ACO is subject to reconciliation and which TINs will be included in reconciliation.

We propose to modify the existing definitions for ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' at § 425.20 to include the following new sentence at the end of each definition: ''An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for a performance year under such initiative during any of the 5 most recent performance years.'' We also propose a technical correction to remove the language ''as defined under this section'' from both definitions. We propose that these amendments would become effective on January 1, 2024.

We seek comments on the proposed regulation text.

7. Proposed Technical Changes to References in Shared Savings Program Regulations

a. References to an ACO's Assignment Methodology Selection

Section 1899(c)(2)(A) of the Act, as amended by the Bipartisan Budget Act of 2018, provides all ACOs with a choice of prospective assignment for agreement periods beginning on or after January 1, 2020. In the December 2018 final rule (83 FR 67859 through 67863), we finalized modifications to the Shared Savings Program's regulations, to separate the choice of beneficiary assignment methodology from the choice of participation track (financial model). We also added a new section of the Shared Savings Program regulations at § 425.226 to govern annual participation elections. In accordance with § 425.226, before the start of a performance year an ACO may make elections related to its participation in the Shared Savings Program, including selection of its beneficiary assignment methodology, which will be effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election. Section 425.226(a)(1) specifies that an ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under subpart E of the Shared Savings Program regulations. An ACO may select either of the following: (i) preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2); or (ii) prospective assignment, as described in § 425.400(a)(3).

For consistency, in the December 2018 final rule (83 FR 67991), we also finalized conforming changes to regulations that previously identified assignment methodologies according to program track. Among other changes to the Shared Savings Program regulations, we added § 425.400(a)(4)(ii) to establish that for agreement periods beginning on July 1, 2019, and in subsequent years, the ACO may select the assignment methodology CMS employs for the assignment of beneficiaries. As specified in § 425.400(a)(4)(ii)(B), this selection of assignment methodology is made prior to the start of each agreement period, and may be modified prior to the start of each performance year as specified in § 425.226 (83 FR 67863).

Although §§ 425.226(a)(1) and 425.400(a)(4)(ii) both reference assignment methodology selection, there are key differences in the purpose each section serves in directing action from the ACO versus action that CMS initiates. Section 425.226 states that the initial selection of, and any annual selection for a change in, beneficiary assignment methodology by an ACO, must be made in the form and manner, and according to the timeframe, that we establish. Therefore, § 425.226(a)(1) is the relevant regulation for referencing the ACO's option to select and to change its selection of assignment methodology. That is, § 425.226 describes actions for which the ACO is responsible because the ACO is selecting the assignment methodology that will be effective at the beginning of the ACO's agreement period or making a change to the ACO's prior assignment methodology selection that will become effective at the beginning of the next performance year.

In comparison, § 425.400 outlines how we employ the assignment methodology described in §§ 425.402 and 425.404 for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment. Therefore, § 425.400(a)(4)(ii) is the relevant regulation for referencing how we determine the assignment methodology to be used in the referenced program operations or program calculations. That is, § 425.400(a)(4)(ii) governs actions undertaken by us because we are applying the ACO's selected assignment methodology when determining benchmarking, preliminary prospective assignment, retrospective reconciliation, and prospective assignment.

Throughout the current Shared Savings Program regulations text, there are various references to § 425.226(a)(1) or § 425.400(a)(4)(ii). We conducted a review of the Shared Savings Program regulations text to determine whether the existing twelve references to either § 425.226(a)(1) or § 425.400(a)(4)(ii) align with provisions' intended purposes. We also considered the intended purposes of the provisions in

identifying the appropriate cross-reference to include in the proposed new regulation at § 425.655, which is described in section III.G.4.b. of this proposed rule.

We believe the following five references to § 425.400(a)(4)(ii) are consistent with the intended purpose of § 425.400(a)(4)(ii), in referring to how we determine the ACO's chosen assignment methodology for purposes of determining beneficiary assignment or performing certain program calculations: § 425.609(c)(1); § 425.652(a)(5)(v)(A); § 425.652(b)(2)(iv)(A); § 425.654(a)(1)(i); and § 425.656(b)(3).

We believe the following two references to § 425.226(a)(1) are consistent with the intended purpose of § 425.226(a)(1) because the references are used when referring to the ACO's option to change its selection of assignment methodology: § 425.601(a)(9) introductory text; and § 425.652(a)(9) introductory text.

We identified five inconsistencies in references to §§ 425.226(a)(1) and 425.400(a)(4)(ii) that we are proposing to revise in this proposed rule. To follow is a description of the five references we are proposing to revise and the proposed technical changes to the applicable provisions in 42 CFR part 425, subpart G to ensure that the appropriate assignment selection reference is being cited for clarity and consistency.

For performance years starting on January 1, 2019, and subsequent performance years, CMS adds beneficiaries to an ACO's list of assigned beneficiaries based on a beneficiary's designation of an ACO professional as the provider or supplier they consider responsible for coordinating their overall care, if certain conditions are satisfied, including the conditions specified in § 425.402(e)(2)(ii)(A). In accordance with § 425.402(e)(2)(ii)(A), the beneficiary must meet the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). Further, the provision specifies that the exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under § 425.402(e), regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii). The reference to § 425.400(a)(4)(ii) in § 425.402(e)(2)(ii)(A) is not consistent with the intended purpose of the reference the ACO's selected assignment methodology. Therefore, we are proposing to amend § 425.402(e)(2)(ii)(A) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1), for clarity and consistency.

The introductory text of § 425.601(a) (applicable to agreement periods beginning on or after July 1, 2019, and before January 1, 2024) and § 425.652(a) (applicable to agreement periods beginning on January 1, 2024, and in subsequent years) specifies that in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.226(a)(1). Accordingly, the introductory text of § 425.601(a) and § 425.652(a) is describing how we will compute expenditures for beneficiaries that would have been assigned to the ACO based on the assignment methodology selected by the ACO. This provision is referring to how we determine the assignment methodology to be used to identify the beneficiary population that would have been assigned in the three benchmark years, not to the ACO's act of selecting the assignment methodology. Therefore, we are proposing to amend the introductory text of § 425.601(a) and § 425.652(a) by removing the reference to § 425.226(a)(1) and adding in its place a reference to § 425.400(a)(4)(ii), for clarity and consistency.

Section 425.652(a)(9)(ii) specifies that for agreement periods beginning on January 1, 2024, and in subsequent years, when adjusting the benchmark for certain changes during the agreement period, we redetermine the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for the assignment window corresponding to BY3 that is consistent with the assignment window that applies under the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.226(a)(1). In § 425.652(a)(9)(ii) the reference to § 425.226(a)(1) is not consistent with the intended purpose of the reference, which is to specify how we determine the assignment methodology that will be used to identify the assigned beneficiary and assignable beneficiary populations which are in turn used to redetermine the regional adjustment in the event the ACO changes its selected assignment methodology. Therefore, we are proposing to amend § 425.652(a)(9)(ii) by removing the reference to § 425.226(a)(1) and adding in its place the reference to § 425.400(a)(4)(ii), for clarity and consistency.

Section 425.652(a)(9)(iv) describes that for agreement periods beginning on January 1, 2024, and in subsequent years, when adjusting the benchmark for certain changes during the agreement period, we redetermine the proration factor used in calculating the prior savings adjustment under § 425.658(b)(3)(ii) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.400(a)(4)(ii), or changes to the beneficiary assignment methodology under 42 CFR part 425, subpart E. In § 425.652(a)(9)(iv) the reference to § 425.400(a)(4)(ii), is not consistent with the intended purpose of provision, which is to specify that we will redetermine the proration factor used in calculating the prior savings adjustment if the ACO changes its beneficiary assignment methodology selection. Therefore, we are proposing to amend § 425.652(a)(9)(iv) by removing the reference to § 425.400(a)(4)(ii) and adding in its place a reference to § 425.226(a)(1), for clarity and consistency.

We seek comments on these proposed technical changes.

b. Definition of Rural Health Clinic

In the November 2011 final rule, we established a definition for the term ''Rural health center (RHC)'' for the Shared Savings Program at § 425.20.[207] The definition of ''Rural health center (RHC)'' at § 425.20 states that this term has the same meaning given to this term under § 405.2401(b). The term ''Rural health clinic (RHC)'' is defined at § 405.2401(b) to mean a facility that has—

- Been determined by the Secretary to meet the requirements of section

[207] See, for example, 76 FR 67930 through 67932 (discussion of our proposal to define FQHCs and RHCs as these terms are defined in § 405.2401(b)), and 76 FR 67974 and 67975 (finalized regulations text for § 425.20).

1861(aa)(2) of the Act and 42 CFR part 491 concerning RHC services and conditions for approval; and

• Filed an agreement with CMS that meets the requirements in § 405.2402 to provide RHC services under Medicare.

This inconsistency between § 425.20, which inaccurately uses the word ''center,'' and § 405.2401(b), which accurately uses the word ''clinic,'' recently came to our attention. We note that the term ''rural health clinic'' was in use and defined at § 405.2401(b) when we established the term and definition for ''Rural health center (RHC)'' under part 425 with the November 2011 final rule. Furthermore, in the November 2011 final rule (76 FR 67803) we separately established an acronym ''RHCs'' for ''Rural Health Clinics'' in the acronyms list reflecting the accurate term.

To ensure clarity and accuracy, we are proposing to correct the error in the definition for ''Rural health center (RHC)'' at § 425.20 by replacing the word ''center'' with the word ''clinic''. We would like to clarify that all uses of the acronym ''RHC'' or ''RHCs'' throughout Part 425—including in the definition of ''primary care physician'' in § 425.20 as well as in §§ 425.102 and 425.304 and throughout 42 CFR part 425, subpart E—have been interpreted to refer to ''rural health clinic'' or ''rural health clinics'' as defined at § 405.2401(b). Further, we propose to revise the definition of rural health center in § 425.20 to specify that the referenced provision at § 405.2401(b) is within Title 42, Chapter IV of the Code of Federal Regulations. We seek comments on these proposed technical changes.

c. Definition of At-Risk Beneficiary

In the November 2011 final rule (see 76 FR 67974), we established the definition of ''At-risk beneficiary'' at § 425.20, the meaning of which includes, but is not limited to, a beneficiary who—

• Has a high risk score on the CMS–HCC risk adjustment model;

• Is considered high cost due to having two or more hospitalizations or emergency room visits each year;

• Is dually eligible for Medicare and Medicaid;

• Has a high utilization pattern;

• Has one or more chronic conditions;

• Has had a recent diagnosis that is expected to result in increased cost;

• Is entitled to Medicaid because of disability; or

• Is diagnosed with a mental health or substance abuse disorder.

In finalizing modifications to the proposed definition of at-risk beneficiary, we explained that we agreed with commenters that our proposed definition should be expanded to include patients who are entitled to *Medicare* (emphasis added) because of disability (see 76 FR 67950). However, in codifying the relevant regulation text at § 425.20, we inadvertently referred to patients who are entitled to *Medicaid* because of disability (emphasis added). We note that an individual who is entitled to Medicare because of disability and who is also entitled to Medicaid, would be included under the category ''Is dually eligible for Medicare and Medicaid.''

We are proposing to correct the typographical error in the definition for ''At-risk beneficiary'' at § 425.20 by replacing the word ''Medicaid'' in paragraph (7) with the word ''Medicare''. We also propose to adjust inaccurate punctuation in the list of paragraphs within this definition by replacing the period at the end of paragraphs (5) and (6) with a semi-colon. We seek comment on these proposed changes.

d. Updating Terminology in Regulations on Data Sharing With ACOs

It has come to our attention that certain terminology that is used in the data sharing regulations for the Shared Savings Program in 42 CFR part 425, subpart H is outdated or inconsistent with the terminology used elsewhere in the Medicare program and in the HIPAA regulations in 45 CFR part 164. We are proposing technical and conforming changes to § 425.702(c)(1)(ii)(A)(*3*) and § 425.702(c)(1)(ii) for clarity and consistency.

In accordance with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS discontinued the use of Social Security Number-based Health Insurance Claim Numbers (HICNs) as the beneficiary identifier on Medicare cards and replaced that identifier type with Medicare Beneficiary Identifiers (MBIs) by April 2019. MBIs are now used for Medicare transactions like billing, eligibility status, and claim status. All claims with a date of service on or after January 1, 2020, must use the beneficiary's MBI, rather than the HICN.[208] [209] To accommodate this change from HICN to MBI, starting in PY 2018 we revised Shared Savings Program reports providing beneficiary-identifiable information under § 425.702, and claim and claim line feed files with beneficiary identifiable claims data provided under § 425.704, to include a field for the beneficiary's MBI. By the end of PY 2019 we discontinued populating data in the HICN fields. However, when we made this operational update we did not make conforming changes to the regulations text at § 425.702(c)(1)(ii)(A) to revise the list of the four data elements we provide to ACOs on their fee-for-service beneficiary population: (1) beneficiary name; (2) date of birth; (3) HICN; and (4) sex. Therefore, because CMS has discontinued use of the HICN, we propose to revise § 425.702(c)(1)(ii)(A)(*3*) to refer to ''Beneficiary identifier'' instead of ''Health Insurance Claim Number (HICN).'' This change to the regulations text will not change the information that is provided to ACOs pursuant to § 425.702(c)(1)(ii).

Further, we propose to revise the list of purposes in § 425.702(c)(1)(ii) for which an ACO may request certain beneficiary-identifiable data for purposes of population-based activities to better align with the terminology used in the first paragraph of the definition of health care operations at 45 CFR 164.501. Specifically, we propose to remove the reference to ''process development'' and to add in its place a reference to ''protocol development.'' In prior rulemaking, we indicated that ACOs could request beneficiary-identifiable data under § 425.702(c)(1)(ii) for purposes of carrying out population-based activities, including process development, and referred to care coordination processes and required process development under § 425.112 (see 80 FR 32734 and 32735). We do not believe the revision we are proposing would impact ACOs' ability to request data for these types of process development. Rather, activities related to care coordination processes and the development of required processes under § 425.112 would continue to fall within the population-based activities listed in § 425.702(c)(1)(ii) for which an ACO may request data, including protocol development (as added by this proposed revision) and care coordination. This proposed revision would also ensure that the terminology used in § 425.702(c)(1)(ii) is consistent with the language of the proposed new provision at § 425.702(c)(1)(iii) discussed in

[208] CMS, MLN Matters, ''New Medicare Beneficiary Identifier (MBI) Get It, Use It''. Article number SE18006, revised March 19, 2020. Available at *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se18006.pdf.*

[209] *CMS.gov* website, Medicare Beneficiary Identifiers (MBIs), at *https://www.cms.gov/Medicare/New-Medicare-Card.*

section III.G.2.b.(2) of this proposed rule.

We seek comment on these proposed changes.

8. Seeking Comments on Potential Future Developments to Shared Savings Program Policies

a. Background

In an article published on the New England Journal of Medicine's website on April 27, 2022,[210] CMS lays out a vision for how Accountable Care Organizations (ACOs) participating in the Shared Savings Program and in Center for Medicare and Medicaid Innovation (Innovation Center) models can help CMS achieve its goal of having all beneficiaries in the traditional Medicare program cared for by health care providers who are accountable for costs and quality of care by 2030. This article describes a vision for the Shared Savings Program and new Innovation Center models to expand participation in ACOs, strengthen incentives for savings for participants and for Medicare, and make access to ACOs more equitable, including: (1) aligning features of new Center for Medicare and Medicaid Innovation (Innovation Center) models and features in the Shared Savings Program; (2) adopting lessons from the ACO Investment Model to help provide upfront investments for small ACOs that lack experience with performance-based risk; (3) examining benchmarking approaches that could support increased participation, including among organizations serving patients with high costs of care and address the effects of rebasing and regional benchmark adjustments; and (4) examining the use of incentives to recruit health care providers that care for underserved populations to join ACOs, with the goal of closing gaps in outcomes, and asking health care providers to consider beneficiaries' social needs in care plans.

CMS adopted several policies as part of the CY 2023 PFS final rule to advance these goals, including providing advance shared savings payments in the form of advance investment payments to certain new, low-revenue ACOs that they can use to build the infrastructure needed to succeed in the Shared Savings Program and promote equity by holistically addressing beneficiary needs, including social needs; reinstating a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs and shared losses for ENHANCED track ACOs; modifying the benchmarking methodology to strengthen financial incentives for long-term participation by reducing the impact of ACOs' performance and market penetration on their benchmarks; support the business case for ACOs serving high-risk and a high proportion of dually eligible populations to participate; and mitigate bias in regional expenditure calculations for ACOs electing prospective assignment; and expanding opportunities for certain low-revenue ACOs participating in the BASIC track to share in savings.

CMS has also continued to receive significant input from interested parties regarding opportunities to increase participation in ACO initiatives. One such option would be to identify ways that the Shared Savings Program can support ACOs' efforts to strengthen primary care, such as by providing prospective payments for primary care that would reduce reliance on fee-for-service payments and support innovations in care delivery that better meet beneficiary needs and increase access to primary care in underserved communities. Empirical data support the notion that primary care serves as the foundation of high-performing ACOs. ACO performance results have indicated that ACOs comprised of 75 percent or more of primary care clinicians share in savings at almost twice the rate of those ACOs comprised of less than 75 percent primary care clinicians.[211] Another option would be to offer a higher risk track in the Shared Savings Program, on which CMS requests input below.

b. Incorporating a Higher Risk Track Than the ENHANCED Track

Over time, CMS has considered a higher risk Shared Savings Program track under which the shared savings/loss rate would be somewhere between 80 percent and 100 percent (that is, a rate higher than that currently offered under the ENHANCED track) that builds on the experience of the Next Generation ACO (NGACO) and ACO Realizing Equity, Access, and Community Health (ACO REACH) Models. ''Higher risk'' sharing provides a higher level of potential reward which may encourage ACOs that would not otherwise have participated in the Shared Savings Program because of current limitations on potential upside to consider participating. Also, a higher risk sharing model may incentivize participating ACOs to take on more risk (and potential reward) and incentivize ACOs to improve performance in the program, which may result in reduced healthcare costs for Medicare, and more effective, efficient care for beneficiaries. In addition, higher risk sharing may incentivize ACOs to develop new care delivery strategies, such as a focus on specialty care integration and reduced care fragmentation. Offering a higher risk sharing track may also help CMS reach our goal of having all beneficiaries in the traditional Medicare program in a care relationship with a health care provider who is accountable for the costs and quality of their care by 2030 by encouraging efficient ACOs to continue participation in the Shared Savings Program.

Currently, under the Shared Savings Program, ACOs may enter participation agreements under one of two tracks—the BASIC track or the ENHANCED track. The BASIC track allows eligible ACOs to begin under a one-sided model and incrementally transition to higher levels of risk and potential reward through the BASIC track's glide path. The ENHANCED track is a two-sided model that represents the highest level of risk and potential reward currently offered under the Shared Savings Program. The rules governing the participation options available to ACOs and the progression from lower to higher risk for ACOs entering the program are described in § 425.600 of the regulations.

Under the BASIC track, eligible ACOs operate under either a one-sided model or a two-sided model, either sharing savings only or sharing both savings and losses with the Medicare program. Under the BASIC track's glide path, the level of risk and potential reward phases in over the course of an agreement period with the ACO beginning participation under a one-sided model and progressing to incrementally higher levels of risk and potential reward, unless the ACO chooses to begin under a two-sided model and/or progress more quickly than the glide path would require.[212] The glide path includes five levels (Levels A through E). Levels A and B are one-sided models (shared savings only); [213] and Levels C, D, and E are two-sided models (shared savings and shared losses) that provide for

[210] Jacobs D, Rawal P, Fowler L, Seshamani M. Expanding Accountable Care's Reach among Medicare Beneficiaries. *NEJM.org,* April 27, 2022, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2202991.*

[211] Refer to ''Medicare Shared Savings Program Saves Medicare More Than $1.6 Billion in 2021 and Continues to Deliver High-quality Care''—As of August 30, 2022, available at *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-16-billion-2021-and-continues-deliver-high.*

[212] Refer to § 425.600(a)(4)(i).

[213] Refer to §§ 425.600(a)(4)(i)(A)(1), 425.605(d)(1)(i) (Level A); §§ 425.600(a)(4)(i)(A)(2), 425.605(d)(1)(ii) (Level B).

incrementally higher performance-based risk.[214] An ACO in the ENHANCED track operates under a two-sided model, sharing both savings and losses with the Medicare program, for all 5 performance years of the agreement period.

To qualify for a shared savings payment, an ACO must meet a minimum savings rate (MSR) requirement, meet the quality performance standard or alternative quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under 42 CFR part 425.[215] For ACOs meeting the applicable quality performance standard established under § 425.512(a)(2) or § 425.512(a)(4)(i) (for PY 2022 and PY 2023) or § 425.512(a)(5)(i) (for PY 2024 and subsequent performance years), the final shared savings rate is equal to the maximum sharing rate specific to the ACO's track/level of participation as follows: 40 percent for ACOs participating in Level A or Level B of the BASIC track,[216] 50 percent for ACOs participating in Levels C, D, or E of the BASIC track,[217] and 75 percent for ACOs participating in the ENHANCED track.[218] Beginning in PY 2023, ACOs meeting the MSR requirement that do not meet the applicable quality performance standard established under § 425.512(a)(2) or § 425.512(a)(4)(i) or § 425.512(a)(5)(i), as applicable, but meet the alternative quality performance standard described in § 425.512(a)(4)(ii) (for PY 2023) or § 425.512(a)(5)(ii) (for PY 2024 and subsequent performance years) will have the opportunity to share in savings at a lower rate that is scaled by the ACO's quality performance. Additionally, beginning in PY 2024, certain ACOs participating in the BASIC track that do not meet the MSR have the opportunity to share in savings at a rate that is equal to half of the rate to which they would have otherwise been entitled had they met the MSR.[219] CMS computes an ACO's shared savings payment by applying the final sharing rate to the ACO's savings on a first dollar basis (meaning the final sharing rate is applied to the ACO's full total savings amount), with the payment subject to a cap that is equal to 10 percent of the updated benchmark for an ACO in the BASIC track or 20 percent of the updated benchmark for an ACO in the ENHANCED track.[220]

ACOs that operate under a two-sided model and have losses that meet or exceed a minimum loss rate (MLR) must share losses with the Medicare program.[221] Once this MLR is met or exceeded, the ACO will share in losses at a rate determined according to the ACO's track/level of participation, up to a loss recoupment limit (also referred to as the loss sharing limit).[222] In determining shared losses, ACOs participating in Level C, D, or E of the BASIC track are subject to a fixed shared loss rate (also referred to as the loss sharing rate) of 30 percent.[223] ENHANCED track ACOs are subject to a loss rate that is scaled by the ACO's quality performance, subject to a minimum of 40 percent and a maximum of 75 percent.[224]

For agreement periods beginning before January 1, 2024, certain ACOs were only allowed to enter the program in the ENHANCED track, and ACOs entering the program in the BASIC track were limited in how many agreement periods they could participate in the BASIC track before being required to transition to the ENHANCED track. Based on changes finalized in the CY 2023 PFS final rule, for agreement periods starting on January 1, 2024, and in subsequent years, participation in the ENHANCED track will be optional (see 87 FR 69818).

In the NGACO Model, NGACOs were offered the choice between two risk arrangements, partial risk or full risk. Under both arrangements, the NGACO was responsible for 100 percent of performance year expenditures, for services rendered to the NGACO's aligned beneficiaries.[225] Under the partial risk arrangement, the NGACO could receive or owe up to 80 percent of savings/losses, whereas under the full risk arrangement, the NGACO could receive or owe up to 100 percent of savings/losses. To mitigate the ACO's risk of large shared losses, as well as to protect the Medicare Trust Funds against paying out excessive shared savings, NGACOs were required to choose a cap on gross savings/losses. The cap, expressed as a percentage of the benchmark, ranged from 5 percent to 15 percent. The risk arrangement chosen by the NGACO (80 or 100 percent) was applied to gross savings or losses after the application of the cap. In PYs 1–3, a discount was applied to the NGACO's benchmark that was set at a standard 3 percent, with various adjustments, that allowed the final discount to vary from 0.5 percent to 4.5 percent. In PYs 4–6, a discount of 0.5 percent was applied to the benchmark under the partial risk arrangement, and a discount of 1.25 was applied to the benchmark under the full risk arrangement. The purpose of the discount was to ensure that CMS received a financial benefit from any savings achieved by the NGACOs participating in the model.

Under the ACO REACH Model, REACH ACOs are offered the choice of participating under the Global or the Professional Risk Options. As in the NGACO Model, under both risk sharing options, the ACO REACH ACO is responsible for 100 percent of performance year expenditures for services rendered to aligned beneficiaries. Because ACOs electing the Global Risk Option retain up to 100 percent of the savings/losses, a discount is applied to the benchmark to ensure savings are also generated for CMS. Consequently, for ACOs in the Global Risk Option, the benchmark is reduced by a fixed percentage based on the performance year.[226] The benchmark for ACOs participating in the Professional Option does not include this discount, and these ACOs are only eligible to retain 50 percent of savings or owe 50 percent of any losses.

When considering including a higher risk track in the Shared Savings Program, we must balance several factors to protect beneficiaries, ACOs, and the Medicare trust funds. One factor to consider is that there may be selective participation with regard to which ACOs would choose to participate in a

[214] Refer to §§ 425.600(a)(4)(i)(A)(3), 425.605(d)(1)(iii) (Level C); §§ 425.600(a)(4)(i)(A)(4), 425.605(d)(1)(iv) (Level D); §§ 425.600(a)(4)(i)(A)(5), 425.605(d)(1)(v) (Level E).

[215] Refer to §§ 425.100(b), 425.604(c), 425.605(c), 425.606(c), 425.610(c).

[216] Refer to § 425.605(d)(1)(i)(A), (d)(1)(ii)(A).

[217] Refer to § 425.605(d)(1)(iii)(A), (d)(1)(iv)(A), (d)(1)(v)(A).

[218] Refer to § 425.610(d).

[219] Refer to § 425.605(h).

[220] Refer to § 425.605(d); § 425.610(e).

[221] Refer to § 425.100(c).

[222] Refer to § 425.605(d); § 425.610(f), (g).

[223] Refer to § 425.605(d)(1)(iii)(C), (d)(1)(iv)(C), (d)(1)(v)(C).

[224] Refer to § 425.610(f).

[225] In 2020, due to the impacts of the COVID–19 pandemic, NGACOs were offered an optional amendment to the Participation Agreement (PA) for 2020 (PY5). For NGACOs that signed the amendment, CMS removed all beneficiary experience associated with COVID–19 related admissions and retrospectively updated the prospective trend with a regional observed trend. For 2021, CMS modified the NGACO financial methodology to provide financial protection to all NGACOs continuing in the model for PY6. PY6 financial protections included: adoption of an extreme and uncontrollable circumstances policy, under which any shared losses were prorated based on the number of months during the PHE and the number of beneficiaries residing in an impacted area, and all expenses associated with COVID–19 related admissions were removed from both PY expenditures and retrospective trend.

[226] For more details, refer to CMS, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Settlement Overview, available at: *https://innovation.cms.gov/media/document/aco-reach-py2023-fncl-settlement* (see Table 4: Schedule of Discounts by Risk Arrangement).

higher risk track, if offered. For example, Shared Savings Program ACOs that have a history of high levels of shared savings or have received a favorable high regional adjustment to their benchmark may be more likely than other ACOs to switch to the higher risk track upon renewing or early renewing their participation in the program so they can receive additional benefit from the higher levels of potential reward offered in a higher risk track. Section 1899(i)(3) of the Act, grants the Secretary the authority to use other payment models, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Medicare and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model under section 1899(d). We have concerns that introducing a higher risk track would lead to only select ACOs participating, creating benefits limited almost entirely to those ACOs and limited to no benefits gained for beneficiaries or CMS.

Another consideration is that ACOs in a higher risk track could have an increased incentive (relative to existing Shared Savings Program risk models) to avoid high-cost beneficiaries in the performance year in order to maximize their potential shared savings payment or avoid or reduce potential shared losses. The Shared Savings Program truncates individual beneficiary expenditures at the 99th percentile of national Medicare fee-for-service expenditures by enrollment type, which can help to protect ACOs from the impact of expenditure outliers (*i.e.,* prevent a small number of extremely costly beneficiaries from significantly affecting the ACO's per capita expenditures) and reduce the incentive for ACOs to avoid high-cost beneficiaries. As described earlier in this section of this proposed rule, the Shared Savings Program also caps the amount of shared savings an ACO may receive or the amount of shared losses it may owe, which can further discourage beneficiary selection. If introducing a higher risk-track to the program, we would need to consider whether the program's existing approach to expenditure truncation and capping shared savings and shared losses would be sufficient in curbing incentives for ACOs to engage in beneficiary selection in light of the higher potential risk and reward, while ensuring that the new risk model will still be attractive to ACOs and improve the quality and efficiency of the care their assigned beneficiaries receive.

When considering a higher risk track, CMS would need to balance the incentives for ACOs to transition to higher levels of risk and potential reward only when they are very confident it is in their financial interest to do so, with the benefits of increasing ACO participation in the Shared Savings Program and in two-sided accountable care tracks, all while ensuring sufficient financial safeguards against inappropriately large shared losses for ACOs coordinating and improving quality of care for high-cost beneficiaries. We are seeking comment on the following: (1) policies/model design elements that could be implemented so that a higher risk track could be offered without increasing program expenditures; (2) ways to protect ACOs serving high-risk beneficiaries from expenditure outliers and reduce incentives for ACOs to avoid high-risk beneficiaries; and (3) the impact that higher sharing rates could have on care delivery redesign, specialty integration, and ACO investment in health care providers and practices.

c. Increasing the Amount of the Prior Savings Adjustment

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period using the most recent available 3 years of expenditures for Parts A and B services for beneficiaries assigned to the ACO. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, as described in the CY 2023 PFS final rule (87 FR 69898 through 69915), we established a prior savings adjustment that will apply when establishing the benchmark for eligible ACOs entering an agreement period beginning on January 1, 2024, or in subsequent years, to account for the average per capita amount of savings generated during the ACO's prior agreement period.

The prior savings adjustment adopted in the CY 2023 PFS final rule is designed to adjust an ACO's benchmark to account for the average per capita amount of savings generated by the ACO across the 3 performance years prior to the start of its current agreement period for re-entering and renewing ACOs. In the final rule, we explained that reinstituting a prior savings adjustment would be broadly in line with our interest in addressing dynamics to ensure sustainability of the benchmarking methodology. Specifically, such an adjustment would help to mitigate the rebasing ratchet effect on an ACO's benchmark by returning to an ACO's benchmark an amount that reflects its success in lowering growth in expenditures while meeting the program's quality performance standard in the performance years corresponding to the benchmark years for the ACO's new agreement period. We also explained our belief that a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area that result in reducing the regional adjustment added to the historical benchmark.

In the CY 2023 PFS final rule (87 FR 69899), we explained that, in order to mitigate the potential for rebased benchmarks for ACOs that are lower-spending compared with their regional service area and that achieved savings in the benchmark period to become overinflated, we believed that adjusting an ACO's benchmark based on the higher of either the prior savings adjustment or the ACO's positive regional adjustment would be appropriate. We also note that elsewhere in this proposed rule, we have proposed to further mitigate the impacts of the negative regional adjustment when the overall adjustment to an ACO's historical benchmark is negative; however, the negative regional adjustments by enrollment type would continue to be factored in when the overall regional adjustment is positive.

In the CY 2023 PFS final rule (87 FR 69902), we finalized a policy to apply a 50 percent scaling factor to the pro-rated positive average per capita prior savings because we believed it would be important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the applicable performance years under its prior agreement period(s). In response to discussion of this policy in the CY 2023 PFS proposed rule, ACOs and other interested parties commented that we should consider using a higher scaling factor that may more closely match the maximum shared savings rate from an ACO's prior agreement period. However, in the CY 2023 PFS final rule, we reiterated our belief that a 50 percent scaling factor would be appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track (*e.g.,* 40 percent). Additionally, we noted that if we were to finalize a scaling factor that would more closely match the average shared savings rate from an ACO's prior agreement period, many ACOs would

have a scaling factor below 50 percent, which would be less advantageous than the policy that we finalized.

In the CY 2023 PFS final rule (87 FR 69902), we also finalized a policy to calculate the final adjustment to the benchmark by adding the pro-rated average per capita prior savings to the ACO's negative regional adjustment for ACOs that are higher spending relative to their regional service area. Under this policy, we apply the 50 percent scaling factor after offsetting the negative regional adjustment to maximize the portion of the pro-rated average per capita savings that would be added to the negative regional adjustment in determining the final adjustment to the benchmark and strengthen incentives for ACOs to remain in the program.

MedPAC commented on the CY 2023 PFS proposed rule that while the prior savings adjustment is a reasonable policy for mitigating ratcheting effects, implementing both the prior savings adjustment and the regional adjustment policies together would be duplicative. MedPAC also expressed concern that the prior savings adjustment and the regional adjustment could interact in a way that would perpetuate a programmatic bias towards ACOs receiving a positive regional adjustment. In MedPAC's view, many ACOs would receive an inflated prior savings adjustment because the prior savings adjustment would be based on savings achieved using benchmarks already inflated by the regional adjustment. However, we explained in the CY 2023 PFS final rule (87 FR 69913) that because for most ACOs, the positive regional adjustment would exceed the prior savings adjustment, our policy of applying the larger of the regional adjustment and the prior savings adjustment potentially mitigates this concern.

We are seeking comment on potential changes to the 50 percent scaling factor used in determining the prior savings adjustment such as using an average of the ACO's shared savings rates from the 3 years prior to the start of its agreement period, increasing to 75 percent of shared savings achieved if the ACO participated in the ENHANCED track in the 3 years prior to the start of the agreement period, or another value corresponding to the maximum shared savings rate the ACO was eligible to earn in the 3 years prior to the start of the agreement period. We are also seeking comment on potential changes to the positive regional adjustment to reduce the possibility of inflating the benchmark while still mitigating potential ratchet effects on ACO benchmarks.

d. Expanding the ACPT Over Time and Addressing Overall Market-Wide Ratchet Effects

As described in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt the policy under which we update the historical benchmark using a blend of national and regional growth rates. In accordance with § 425.601(b), for agreement periods beginning on July 1, 2019, and before January 1, 2024, we update the historical benchmark for an ACO for each performance year using a blend of national and regional growth rates between BY3 and the performance year.

In the CY 2023 PFS final rule (87 FR 69902), we finalized a policy for agreement periods beginning on January 1, 2024, and in subsequent years to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) that we refer to as the Accountable Care Prospective Trend (ACPT), into a ''three-way'' blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period. The three-way blend is calculated as the weighted average of the ACPT (one-third weight) and the existing national-regional ''two-way'' blend (two-thirds weight). The ACPT will be projected for an ACO's entire agreement period near the start of that agreement period, providing a degree of certainty to ACOs.

We explained in the CY 2023 PFS final rule that the ACPT will insulate a portion of the annual benchmark update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and address the impact of increasing market penetration by ACOs in a regional service area on the existing blended national-regional growth factor. Because the ACPT is prospectively set at the outset of an agreement period, any savings generated by ACOs during the agreement period would not be reflected in the ACPT component of the three-way blend. Accordingly, incorporation of the ACPT may allow benchmarks to increase beyond actual spending growth rates as ACOs slow spending growth. By limiting ACOs' ability to slow spending growth for purposes of their own benchmarks, we noted that we believed the use of this three-way blend to update ACOs' benchmarks would incentivize greater savings by ACOs and greater program participation. Additionally, because incorporating the ACPT into the update would reduce the degree to which an ACO's savings negatively impact its benchmark through the regional trend component of the update, we also stated our belief that this change to the update methodology would help to address concerns raised by ACOs and other interested parties regarding the disproportionate impact of an ACO's savings on the benchmark update for ACOs with high market share.

In the final rule, we noted that it was possible that incorporating the ACPT into a three-way blended update factor would have the potential for mixed effects. For example, it may also lower an ACO's benchmark relative to the two-way blend if external factors lead to higher program spending growth than originally projected at the start of an ACO's agreement period. Consequently, we finalized that if an ACO generates losses for a performance year that meet or exceed its MLR (for two-sided model ACOs) or negative MSR (for one-sided model ACOs) under the three-way blend, we would recalculate the ACO's updated benchmark using the two-way blend and the ACO would receive whichever benchmark update minimizes shared losses. However, the ACO would not be eligible to share in savings resulting from use of the two-way blend in updating the benchmark. We also finalized that if unforeseen circumstances such as an economic recession, pandemic, or other factors cause actual expenditure trends to significantly deviate from projections, we would retain discretion to decrease the weight applied to the ACPT in the three-way blend.

In their comments on the proposal to adopt the three-way blend in the CY 2023 PFS proposed rule, ACOs and other interested parties expressed concern that the three-way blend effectively increases the proportion of the benchmark update that is based upon national trends, as opposed to regional trends, noting that the blend may not adequately account for geographic variation in spending growth that is outside of an ACO's control. Over a 5-year agreement period, we recognize some ACOs may be disadvantaged or advantaged in the short term by benchmark updates that give greater weight to a national update factor. However, as we stated in the CY 2023 PFS final rule (87 FR 69891), we believe that the net impact of these deviations will be modest in the context of offsetting considerations. For example, the three-way blend only incorporates the ACPT at a one-third weight and maintains the current two-way blend for the majority weight of the benchmark trend calculation, allowing for a

significant proportion of the benchmark update to reflect expenditure growth in an ACO's regional service area. The ACPT itself is also expected to project spending above realized spending as ACOs generate savings, thereby providing a stable, predictable component of the update factor that will be beneficial for ACOs.

Interested parties who commented on the proposal in the CY 2023 PFS proposed rule to incorporate the ACPT as part of a three-way blend suggested modifications to the three-way blend to further mitigate potential ratchet effects and to better reflect regional variation in spending. These included modifications such as: (1) keeping a two-way national-regional blend and substituting the national component of the two-way blend with the ACPT (see 87 FR 69890); and (2) adjusting the weight of the ACPT in the three-way blend to reflect each ACO's market penetration, as is done with the national component of the two-way blend (see 87 FR 69893). CMS declined to implement these suggestions in the CY 2023 PFS final rule.

We seek comment on the following potential refinements to the ACPT and the three-way blended benchmark update factor as CMS works toward broad implementation of administrative benchmarks: (1) replacing the national component of the two-way blend with the ACPT; and (2) scaling the weight given to the ACPT in a two-way blend for each ACO based on the collective market share of multiple ACOs within the ACO's regional service area.

e. Promoting ACO and CBO Collaboration

Section 1899(b)(2)(G) of the Act requires an ACO to define processes to promote evidence-based medicine and patient engagement; report on quality and cost measures; and coordinate care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies. In the November 2011 final rule (76 FR 67827), we finalized policies to require that a participating Shared Savings Program ACO provide documentation in its application describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. We emphasized our belief that ACOs should retain the flexibility to establish processes that are best suited to their practice and patient population. As part of these required processes, we explained that ACOs should adopt a focus on patient-centeredness, which could include such activities as: a process for evaluating the needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of this population, including how the ACO intends to partner with other interested parties in the community to improve the health of its population; a plan to engage in shared decision making with beneficiaries; and a plan to implement individualized care plans, including taking into account the community resources available to the individual beneficiary.

When establishing these required processes and patient centeredness criteria in the November 2011 final rule (76 FR 67826), we stated that as we learn more about successful strategies in these areas, and as we gain more experience assessing specific critical elements for success, the Shared Savings Program eligibility requirements under section 1899(b)(2)(G) of the Act may be revised. For example, in subsequent rules we underscored the importance of health information technology development and infrastructure within care coordination. In the June 2015 final rule, we finalized two modifications to the care coordination processes required of ACOs under § 425.112(b)(4): (1) adding a new eligibility requirement under § 425.112(b)(4)(ii)(C), which required an ACO to describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries, and (2) adding a new provision at § 425.112(b)(4)(ii)(D), which required the applicant to describe how the ACO intends to partner with long-term and post-acute care providers to improve care coordination for the ACO's assigned beneficiaries (80 FR 32725). In the CY 2018 PFS final rule (82 FR 53222), we shifted from requiring an ACO to submit documents detailing how it would meet the requirements of § 425.112 as a narrative in its Shared Savings Program application to instead requiring it to certify at the time of application that it has defined the required processes and patient centeredness criteria consistent with the requirements specified in section § 425.112 and to furnish such documentation upon request—thereby reducing ACO burden while maintaining CMS's flexibility to obtain additional documentation when necessary (see § 425.204(c)(ii)).

Additionally, in previous rulemaking (80 FR 32722), we specified that the care coordination processes under § 425.112 could include coordination with CBOs that provide services that address social determinants of health. This coordination could include a plan to partner with interested parties of the community, a plan to engage in shared decision making with beneficiaries, and a plan to implement individualized care plans. In that rulemaking (80 FR 32722), we also confirmed our understanding that ACOs differ in their ability to adopt the appropriate health information exchange technologies, but we continued to underscore the importance of robust health information exchange tools in effective care coordination.

We are seeking comment on ways to improve and incentivize collaboration between ACOs and interested parties in the community or CBOs. As explained in the CY 2023 PFS final rule (87 FR 69790), where we refer to CBOs, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), or the Centers for Disease Control, or from State-funded grants to provide social services. Generally, we believe such organizations are trusted entities that know the populations they serve and their communities, want to be engaged, and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health or serve as a trusted source to share information.[227] We recognize that ACOs wishing to address social needs may want to make investments in goods or social services that would enable their ACO participants and ACO providers/suppliers to work with CBOs that have expertise in identifying and providing the types of social services that the ACO's beneficiary population requires.

It is important to note that the Shared Savings Program does not prohibit ACOs from partnering with CBOs. Currently, if a CBO is enrolled in Medicare, it may already be an ACO participant or an ACO provider/supplier. We believe CBOs could play

[227] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Preparedness and Response, Community-Based Organizations during COVID–19, available at *https://www.phe.gov/emergency/events/COVID19/atrisk/returning-to-work/Pages/default.aspx*.

an important role in identifying and addressing gaps in health equity. As we stated in the CY 2023 PFS final rule, we hope to encourage more ACOs to partner with CBOs whether they provide items and services reimbursed by Medicare or not. We recognized that Federal and other sources of grant funding for social services may be insufficient to fully address the demand for services within a community or broader geography. As we noted in that final rule, contractual arrangements between the health care sector and CBOs providing social services have increased in recent years to meet this demand.

We are seeking comment on approaches, generally, for encouraging or incentivizing increased collaboration between ACOs and CBOs, including any policies specifically designed to encourage ACOs to partner with CBOs and address unmet health-related social needs. We are also seeking comment on potential changes CMS could make to the patient-centered care requirements in § 425.112 to strengthen partnerships between ACOs and interested parties in the community, including CBOs, to address unmet health-related social needs.

H. Medicare Part B Payment for Preventive Vaccine Administration Services (§§ 410.10, 410.57, 410.152)

1. Statutory Background

Under section 1861(s)(10) of the Act, Medicare Part B currently covers both the vaccine and vaccine administration for the specified preventive vaccines—the pneumococcal, influenza, hepatitis B and COVID–19 vaccines. Section 1861(s)(10)(B) of the Act specifies that the hepatitis B vaccine and its administration is only covered for those who are at high or intermediate risk of contracting hepatitis B, as defined at § 410.63. Under sections 1833(a)(1)(B) and (b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccines or the services to administer them. Per section 1842(o)(1)(A)(iv) of the Act, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for the vaccine product, except where furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or Federally qualified health center (FQHC). Some other preventive vaccines, such as the zoster vaccine for the prevention of shingles, not specified for Medicare Part B coverage under section 1861(s)(10) of the Act are instead covered and paid for under Medicare Part D.

2. Medicare Part B Payment for the Administration of Preventive Vaccines

a. Pneumococcal, Influenza and Hepatitis B Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65186), we finalized a uniform payment rate of $30 for the administration of a pneumococcal, influenza or hepatitis B vaccine covered under the Medicare Part B preventive vaccine benefit. We explained that since the administration of the preventive vaccines described under section 1861(s)(10) of the Act are finalized independent of the PFS, these payment rates will be updated as necessary, independent of the valuation of any specific codes under the PFS. (Please see COVID–19 vaccine administration payment information in the next section.) The CY 2022 PFS final rule (86 FR 65180 through 65182) provides a detailed discussion on the history of the valuation of the three Level II Healthcare Common Procedure Coding System (HCPCS) codes, G0008, G0009, and G0010, which describes the services to administer an influenza, pneumococcal, and hepatitis B vaccine, respectively.

In the CY 2023 PFS final rule (87 FR 69984), we finalized an annual update to the payment amount for the administration of Part B preventive vaccines based upon the percentage increase in the Medicare Economic Index (MEI). Additionally, we finalized the use of the PFS Geographical Adjustment Factor (GAF) to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered. These adjustments and updates apply to HCPCS codes G0008, G0009, G0010, and to Level I Current Procedural Terminology (CPT) codes that describe the service to administer COVID–19 vaccines, which we discuss in the next section.[228]

The current payment rates for G0008, G0009, and G0010, as finalized in the CY 2023 PFS final rule, can be found on the CMS Seasonal Influenza Vaccines Pricing website under Downloads.[229] The payment rates for these services with the annual update applied for CY 2024, will be made available at the time of publication of the CY 2024 PFS final rule.

b. COVID–19 Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65181 and 65182), we provide a detailed history regarding the determinations of the initial payment rates for the administration of the COVID–19 vaccines, and how the payment policy evolved to a rate of $40 per dose. We note that in the CY 2022 PFS proposed rule (86 FR 39220 through 39224), we included a comment solicitation requesting information that specifically identifies the resource costs and inputs that should be considered when determining payment rates for preventive vaccine administration. As part of the comment solicitation, we requested feedback specifically related to the circumstances and costs associated with furnishing COVID–19 vaccines, in order to ensure that we took these into consideration when determining our payment policy. In the CY 2022 PFS final rule (86 FR 65185), we stated that, after consideration of all the comments received, it was appropriate to establish a single, consistent payment rate for the administration of all four Part B preventive vaccines in the long term, but to pay a higher, $40 payment rate for administration of COVID–19 vaccines in the short term, while pandemic conditions persisted (86 FR 65185).

In the CY 2023 PFS final rule (87 FR 69988 through 69993), we stated that in light of the timing distinctions between a PHE declared under section 319 of the Public Health Service (PHS) Act and an Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), we reconsidered the policies finalized in the CY 2022 PFS final rule in light of our goal to promote broad and timely access to COVID–19 vaccines. We explained that our goal would be better served if our policies with respect to payment for these products, as addressed in the November 2020 IFC and CY 2022 PFS final rule, continue until the EUA declaration for drugs and biological products with respect to COVID–19 (see 85 FR 18250) is terminated. Therefore, we finalized that we would maintain the current payment rate of $40 per dose for the administration of COVID–19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, the COVID–19 vaccine administration

[228] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[229] *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice/vaccinespricing.*

payment would be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines, that is, $30 per dose. As mentioned above, we also finalized that, beginning January 1, 2023, we would annually update the payment amount for the administration of all Part B preventive vaccines based upon the percentage increase in the MEI, and that we would use the PFS GAF to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the vaccine is administered.

The current payment rates for the CPT codes that describe the service to administer COVID–19 vaccines, as finalized in the CY 2023 PFS final rule, can be found on the CMS COVID–19 Vaccines and Monoclonal Antibodies website.[230] The payment rates for these services with the annual update applied for CY 2024, will be made available at the time of publication of the CY 2024 PFS final rule.

3. In-Home Additional Payment for Administration of COVID–19 Vaccines

a. Background

In the CY 2022 PFS final rule (86 FR 65187 and 65190), we provide a detailed discussion on the payment policy for COVID–19 vaccine administration in the home. In summary, providers and suppliers that administer a COVID–19 vaccine in the home, under certain circumstances, can bill Medicare for one of the existing COVID–19 vaccine administration CPT codes[231] along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). In CY 2022, the Medicare Part B payment amount paid to providers and suppliers administering a COVID–19 vaccine in the home was $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home). These payment amounts were then geographically adjusted using PFS GPCIs (as discussed in the CY 2023 PFS final rule at 87 FR 69980 through 69983).

Since announcing the add-on payment for in-home COVID–19 vaccine administration in June 2021, we noted that we established these policies on a preliminary basis to ensure access to COVID–19 vaccines during the public health emergency and that we would continue to evaluate the needs of Medicare patients and these policies. In the CY 2022 PFS proposed rule (86 FR 39224 through 39226), we included a comment solicitation to collect feedback on these policies and potential future changes. As part of the comment solicitation, we requested feedback related to our definition of ''home,'' program integrity concerns, changes that we should consider, costs associated with administering COVID–19 vaccines in the home, and whether outside of a PHE there is a need to vaccinate people in the home rather than going to a health care provider or supplier. In the CY 2022 PFS final rule (86 FR 65188 through 65190), we discussed the feedback received, and we noted that commenters overwhelmingly recommended that we continue making the additional payment for COVID–19 vaccines administered in the home beyond the end of the PHE. Many commenters also supported extending the payment to other preventive vaccines, either permanently or until the end of the PHE. Commenters emphasized the importance of increasing vaccination rates and making vaccines available to underserved homebound beneficiaries who face barriers including chronic illness, financial and social precarity, and lack of access to digital resources. We agreed with commenters that the added costs and compelling needs required CMS to adopt the in-home add-on payment rate for COVID–19 vaccine administration. In addition, we stated that since we did not expect those needs or costs to diminish immediately with the end of the PHE, we believed it would be appropriate to leave the in-home add-on payment rate in place through the end of the calendar year in which the PHE ends. We explained that this extension of payment past the end of the PHE would also afford CMS the opportunity to monitor vaccine uptake data (86 FR 65189). We note that in section III.H.3.c. of this proposed rule, we are proposing revisions to § 410.152 that relate to this payment policy.

In the CY 2023 PFS final rule (87 FR 69984 through 69986), we discussed that we had received many comments and requests from interested parties that the in-home add-on payment be applied more broadly to all preventive vaccines. Commenters also expressed concerns that discontinuation of the in-home additional payment would negatively impact access to the COVID–19 vaccine for underserved homebound beneficiaries. We noted that while we agreed with these concerns, we also believed that we need to learn more about the populations served through the current in-home add-on payment, and other potential populations that may not have been able to access a COVID–19 vaccine despite the availability of the in-home add-on payment, in order to understand the barriers in receiving vaccinations in their home versus in the community. We also noted the need to consider potential program integrity concerns. Therefore, we finalized that we would continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home, under the certain circumstances described in section III.H.3.b of the final rule, only for the duration of CY 2023. We explained that we were continuing the additional payment for at-home COVID–19 vaccinations for another year in order to provide us time to track utilization and trends associated with its use, in order to inform the Part B preventive vaccine policy on payments for in-home vaccine administration for CY 2024.

We also finalized the policy to adjust this payment amount for geographic cost differences as we do the payment for the preventive vaccine administration service, that is, based upon the fee schedule area where the COVID–19 vaccine is administered, by using the PFS GAF. In addition, we finalized an update to the $35.50 payment amount by the CY 2023 MEI percentage increase, consistent with the policy finalized for the other preventive vaccine administration services. We note that in the CY 2023 PFS final rule (87 FR 69688 through 69710), we rebased and revised the MEI to a 2017 base year. Therefore, we finalized (87 FR 69986) that for CY 2023, the in-home additional payment amount for COVID–19 vaccine administration described by HCPCS code M0201 was $36.85 ($35.50 × 1.038 = $36.85), and we established that payment for these services is adjusted for geographic cost differences using the relevant PFS GAF. We note that in section III.H.3.c. of this proposed rule, we are proposing revisions to § 410.152 that relate to these policies.

b. Conditions for Billing HCPCS Code M0201

In establishing the additional payment for COVID–19 vaccine administration in the home, we also established certain conditions for the add-on payment described by HCPCS code M0201. In the CY 2022 PFS final rule, we provide a detailed discussion

[230] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

[231] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

on how we established the certain conditions under which the code can be used, and the situations we contemplated to arrive at our final payment policy (86 FR 65187 and 65188).

For purposes of this add-on payment for in-home COVID–19 vaccine administration, the following requirements apply when billing for HCPCS code M0201: [232] [233]

- The patient has difficulty leaving the home to get the vaccine, which could mean any of these:

++ They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;

++ They have a condition that makes them more susceptible to contracting a pandemic disease like COVID–19; or

++ They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.

- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.
- The sole purpose of the visit is to administer the COVID–19 vaccine. Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.
- A home can be:

++ A private residence, temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter);

++ An apartment in an apartment complex or a unit in an assisted living facility or group home (including assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program);

++ A patient's home that is made provider-based to a hospital during the PHE for COVID–19; or

++ Communal spaces of a multi-unit or communal living arrangement.

- A home cannot be:

++ An institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and skilled nursing facilities (SNFs), as well as most nursing facilities under Medicaid.[234]

The COVID–19 vaccine must be administered inside an individual's home. For this purpose, an individual unit in a multi-dwelling building is considered a home. For example, an individual apartment in an apartment complex or an individual bedroom inside an assisted living facility or group home is considered a home. HCPCS code M0201, as noted in the code descriptor, can be billed only once per individual home per date of service. Medicare pays the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location.

c. Proposals for CY 2024 and Subsequent Years

Over the past several months, CMS has engaged in an in-depth analysis of the use of HCPCS billing code M0201, which specifically indicates that a COVID–19 vaccine was furnished in the home on a Medicare claim. The analysis found that data for in-home COVID–19 vaccinations among Medicare fee-for-service beneficiaries from June 2021 to June 2022 show the payment code was used at a disproportionately high rate by underserved populations, including persons who are dual eligible for both Medicare and Medicaid and those of advanced age. The data reflect that, between June 2021-June 2022, those 85 years of age and older were over 3 times more likely than younger beneficiaries to have received an in-home COVID–19 vaccination, and persons who are dual eligible for both Medicare and Medicaid were over 2 times more likely than those who are not dual eligible to have received a COVID–19 vaccine provided in their home. The data also showed higher usage of the in-home payment code among those with some common chronic conditions.[235]

In light of the results of our study, we concluded that the in-home additional payment improved healthcare access to vaccines for these often-underserved Medicare populations. From an analysis of the data, it is clear that the in-home additional payment is being billed significantly more frequently for beneficiaries that are harder to reach and that may be less likely to otherwise receive these preventive benefits. Therefore, we propose to maintain the in-home additional payment for COVID–19 vaccine administration under the Part B preventive vaccine benefit. In addition, since our statutory authority at section 1861(s)(10) of the Act to regulate Part B preventive vaccine administration is identical for all four preventive vaccines, and since the payment has been shown to positively impact health equity and healthcare access, we propose to extend the additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit—the pneumococcal, influenza, and hepatitis B vaccines. We propose to provide the additional payment for pneumococcal, influenza, hepatitis B and COVID–19 vaccine administrations in the home, when the conditions described in section III.H.3.b of this proposed rule are met. We note that several of the conditions we established for the in-home additional payment, discussed previously in this section of the proposed rule, refer specifically to COVID–19. If we finalize the proposal to expand the in-home additional payment to the other preventive vaccines, we would broaden the conditions for the payment to reflect preventive vaccines for the other diseases.

Further, since expanding this policy could mean that multiple vaccines are administered during the same visit to the home, we propose to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit. We emphasize that every vaccine dose that is furnished would still receive its own unique vaccine administration payment. We intend to continue to monitor utilization of the M0201 billing code for the in-home additional payment, and we plan to revisit the policy should we observe inappropriate use or abuse of the code. We propose to modify the regulations at § 410.152(h) to reflect these policies.

We seek comment on the policy condition mentioned in section III.H.3.b of this proposed rule regarding Medicare payment of the in-home additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location, but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location. We invite feedback on the applicability of this policy to the proposed policy to make

[232] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[233] *https://www.cms.gov/files/document/vaccine-home.pdf.*

[234] 42 CFR 409.42(a).

[235] Common chronic conditions as identified by the CMS Chronic Conditions Data Warehouse, *https://www2.ccwdata.org/web/guest/home/.*

the in-home additional payment available for the administration of all four Part B preventive vaccines.

If finalized as proposed, the in-home additional payment for the administration of pneumococcal, influenza, and hepatitis B vaccines would be effective January 1, 2024, to join the current additional payment for the in-home administration of COVID–19 vaccines that is now being extended. That is, providers and suppliers would continue to bill Medicare Part B for the additional payment for the in-home administration of COVID–19 vaccines, and beginning January 1, 2024, they would also be able to bill Medicare Part B for the in-home administration of pneumococcal, influenza, and hepatitis B vaccines. In addition, like the current in-home additional payment for COVID–19 vaccine administration, the proposed in-home additional payment for the administration of Part B preventive vaccines that would be effective beginning for CY 2024, if finalized, would be geographically adjusted based on the PFS GAF, and annually updated by the CY 2024 MEI percentage increase. For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through fourth quarter 2022. Therefore, we would multiply the CY 2023 in-home additional payment amount for Part B preventive vaccine administration of $36.85 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent, which would result in a proposed CY 2024 in-home additional payment for Part B preventive vaccine administration of $38.51 ($36.85 x 1.045 = $38.51). We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the MEI percentage increase), we would use such data, if appropriate, to determine the CY 2024 MEI percentage increase in the CY 2024 PFS final rule; we would apply that new MEI percentage increase to update last year's $36.85 CY 2023 in-home additional payment amount for Part B preventive vaccine administration.

Therefore, in this proposed rule, we propose to amend the Part B payment for preventive vaccine administration regulations at § 410.152(h) to reflect the following:

- Effective January 1, 2022, the Medicare Part B additional payment amount paid to providers and suppliers administering a COVID–19 vaccine in the home, under certain circumstances, is $35.50. For COVID–19 vaccines administered in the home January 1, 2022 through December 31, 2022, the additional payment amount under Medicare Part B is adjusted to reflect geographic cost variations using the PFS GPCIs.
- Effective January 1, 2023, the additional payment amount for the administration of a COVID–19 vaccine in the home is annually updated based upon the percentage change in the MEI. For COVID–19 vaccines administered in the home January 1, 2023 through December 31, 2023, the payment amount is adjusted to reflect geographic cost variations using the PFS GAF.
- Effective January 1, 2024, the payment policy allowing for additional payment for the administration of a COVID–19 vaccine in the home would be extended to include the other three preventive vaccines included in the Part B preventive vaccine benefit, and the payment amount for all four vaccines would be identical. That is, beginning January 1, 2024, the Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID–19 vaccine in the home, under certain circumstances. This additional payment amount would be annually updated using the percentage increase in the MEI and adjusted to reflect geographic cost variations using the PFS GAF.

We solicit comment on these proposals and the proposed amendments to the regulation text.

4. Other Amendments to Regulation Text

In CY 2023 PFS final rule (87 FR 69987 through 69993), we finalized changes to our policies regarding Part B coverage and payment for COVID–19 monoclonal antibody products and their administration. In that final rule (87 FR 69987), we discussed that all COVID–19 monoclonal antibody products and their administration are covered and paid for under the Part B preventive vaccine benefit through the end of year in which the Secretary terminates the EUA declaration for drugs and biological products with respect to COVID–19. In addition, we explained that, under the authority provided by section 3713 of the CARES Act, we have established specific coding and payment rates for the COVID–19 vaccine, as well COVID–19 monoclonal antibodies and their administration, through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website (87 FR 69987). At 87 FR 69983, we listed the unique payments rates for the administration of COVID–19 monoclonal antibodies in Table 85. We note that at the time of the publication of this proposed rule, there are no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States.

In the CY 2023 PFS final rule, we also established a policy to continue coverage and payment for monoclonal antibodies that are used for pre-exposure prophylaxis (PreP) of COVID–19 under the Part B preventive vaccine benefit, if they meet applicable coverage requirements (87 FR 69992). We explained that we would continue to pay for these products and their administration even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization. Additionally, we established that payments for the administration of monoclonal antibodies that are used for PreP of COVID–19 would be adjusted for geographic cost variations using the PFS GAF. However, we did not codify these policies in our regulations. We now propose revisions to the relevant regulations to include monoclonal antibodies that are used for PreP of COVID–19 under the Part B preventive vaccine benefit. Specifically, we propose to revise the following regulations to reflect policies for monoclonal antibodies for PreP of COVID–19 that we finalized in the CY 2023 PFS final rule:

- At § 410.10, in paragraph (l), we propose to add a phrase regarding monoclonal antibodies used for pre-exposure prophylaxis of COVID–19, and their administration.
- At § 410.57, in paragraph (c), we propose to add a phrase regarding monoclonal antibodies used for pre-exposure prophylaxis of COVID–19, and their administration.

We note again that at the time of the publication of this proposed rule, there are no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States. Therefore, we are not proposing any payment regulations regarding monoclonal antibodies for PreP of COVID–19 at this time. If and when a new monoclonal antibody for PreP of COVID–19 becomes authorized for use, we would use the authority provided by section 3713 of the CARES Act, as discussed in the CY 2023 PFS Final Rule (87 FR 69987), to establish specific coding and payment rates for the administration of that product through technical direction to MACs and information posted publicly on the CMS website. We would subsequently

propose coding and payment rates for the administration of that product via rulemaking.

We also note that, for the purposes of the in-home additional payment discussed above in section III.H.3.c. of this proposed rule, that additional payment is not applicable to the administration of monoclonal antibodies for PreP of COVID–19. With regard to monoclonal antibodies for PreP of COVID–19, as displayed in Table 85 of the CY2023 PFS final rule (87 FR 69983), we set the coding and payment rates for the administration of COVID–19 monoclonal antibodies in the home to be higher than those in other health care settings, and therefore such amounts already account for the higher costs of administering the product in the home. More information on our coding and payment policies for COVID–19 monoclonal antibodies is available at *https://www.cms.gov/monoclonal*.

Also, in the CY 2023 PFS final rule, we codified our payment rates for all four Part B preventive vaccines, and we finalized that the vaccine administration payment rates for all four Part B preventive vaccines would be annually updated by the MEI and geographically adjusted by the PFS GAF. We included these policies in regulation text at § 410.152(h). However, we neglected to include the effective date for the MEI policy in the regulation text. We are proposing the following correction, and we are reorganizing other elements of the regulation text at § 410.152(h) as we codify the in-home additional payment:

- At § 410.152, at paragraph (h)(5), we propose to add that the paragraph is effective beginning January 1, 2023.
- At § 410.152, we propose to combine the existing paragraph (h)(2) and (h)(3) into a new paragraph (h)(2), with subparagraphs (h)(2)(i) and (h)(2)(ii)
- At § 410.152, at a revised paragraph (h)(3), we propose new regulations regarding the in-home additional payment for preventive vaccine administration, as described in this section of the proposed rule in section III.H.3.c.

I. Medicare Diabetes Prevention Program (MDPP)

The Centers for Medicare & Medicaid Services' (CMS) Medicare Diabetes Prevention Program Expanded Model (hereafter, ''MDPP'' or ''expanded model'') is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. MDPP is an expansion in duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested by CMS through a Round One Health Care Innovation Award (2012–2016). MDPP was established in 2017 as an ''additional preventive service'' covered by Medicare and not subject to beneficiary cost-sharing, in addition to being available once per lifetime to eligible beneficiaries. To facilitate delivery of MDPP in a non-clinical community setting (to align with the certified DPP model test) by non-clinical providers, CMS created through rulemaking in the CY 2017 PFS final rule, a new MDPP supplier type, in addition to requiring organizations that wish to participate in MDPP enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes.

MDPP is a non-pharmacological behavioral intervention consisting of no fewer than 22 intensive sessions using a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Program (National DPP) curriculum. Sessions are furnished over 12 months by a trained Coach who provides training on topics that include long-term dietary change, increased physical activity, and behavior change strategies for weight control and diabetes risk reduction. Suppliers may use the CDC-developed PreventT2 curriculum [236] or an alternate CDC-approved curriculum when delivering MDPP. The primary goal of the expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss.

Eligible organizations seeking to furnish MDPP began enrolling in Medicare as MDPP suppliers on January 1, 2018 and began furnishing MDPP on April 1, 2018. Through the National DPP Diabetes Prevention Recognition Program (DPRP), the CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence-based DPRP Standards,[237] which are updated every 3 years. The CDC established the DPRP in 2012 and possesses significant experience assessing the quality of program delivery by organizations throughout the United States, applying a comprehensive set of national quality standards. For further information on the DPP model test, the CDC's National DPP, and DPRP Standards, please refer to the CY 2017 [238] and CY 2018 PFS [239] final rules and the following websites: *https://Innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/*; *https://www.cdc.gov/diabetes/prevention/index.html*; and *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

We are proposing to amend § 410.79(b) to remove the definition for the core maintenance session interval while adding definitions for the following terms: Combination delivery, Distance learning, Extended flexibilities, Extended flexibilities period, Full-Plus CDC DPRP recognition, Online delivery, and Virtual sessions. In addition, we propose to amend § 410.79(c)(2)(i)(A) and (B) to update the maximum number of payable sessions during the MDPP core services period. We also propose to amend § 410.79(e)(2) to extend certain flexibilities established through rulemaking as a result of the recent COVID–19 public health emergency (PHE) for a period of 4 years. Furthermore, we propose to amend § 414.84 to streamline the MDPP payment structure by adding service-based attendance payments, while still retaining the diabetes risk reduction performance payments for 5 percent and 9 percent weight loss. We also propose to amend § 424.205(a) and (c) to remove ''MDPP interim preliminary recognition'' and replace it with ''CDC preliminary recognition''.

1. Proposed Changes to § 410.79 by Amending Paragraphs (b), (c)(2)(i) and (e)(2)

The MDPP expanded model was implemented through the rulemaking process in two phases in the CY 2017 PFS final rule [240] and in the CY 2018 PFS final rule.[241] Through this proposed rule, we are proposing to amend the MDPP expanded model to revise certain

[236] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html*.

[237] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

[238] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements. 81 FR 80471. Accessed March 12, 2023. *https://www.govinfo.gov/content/pkg/FR–2016–11–15/pdf/2016–26668.pdf*.

[239] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 FR 52976. *https://www.govinfo.gov/content/pkg/FR–2018–11–23/pdf/2018–24170.pdf*.

[240] *https://www.govinfo.gov/content/pkg/FR–2016–11–15/pdf/2016–26668.pdf*.

[241] *https://www.govinfo.gov/content/pkg/FR–2017–11–15/pdf/2017–23953.pdf*.

MDPP policies adopted through previous rulemaking. We are proposing to amend § 410.79(b) to remove the definition for the core maintenance session interval while adding definitions for Combination delivery, Distance learning and Online delivery modalities, among other definitions. The core maintenance session interval, as defined in the CY 2018 PFS, means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month. The core maintenance session interval represents a performance interval for attendance-based payments in the current payment structure. Given that we are proposing that beneficiary attendance be paid on a fee-for-service basis, we propose removing the core maintenance session interval to make the payment structure less confusing.

In prior rulemaking, we did not formally define the MDPP delivery modalities that are considered virtual. In this proposed rule, we propose adding definitions for distance learning and online delivery modalities in § 410.79(b) to better clarify which virtual modalities can be used in the proposed Extended flexibilities period.

We are also proposing to modify the definitions for Make-up session, MDPP services period, and MDPP session as defined in § 410.79(b) to remove most references to ongoing maintenance sessions. In the CY 2022 PFS, we removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Given that the 2-year MDPP services period for those beneficiaries who started MDPP on or before December 31, 2022 will end on or before December 30, 2024, eligibility for ongoing maintenance services will end December 31, 2023 for all beneficiaries.

The core services period, as defined in § 410.79(c)(2)(i)(A) and (B), consists of at least 16 core sessions offered at least one week apart during the months 1 through 6 of the MDPP services period, and two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period. In order to conform to the proposed revisions to the payment structure in § 414.84, we are proposing to amend the expanded model regulations to allow for fee-for-service payments for beneficiary attendance during the core services period.

MDPP's performance-based payment structure was established in the CY 2018 PFS to pay for the Set of MDPP services that makes up the periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all MDPP performance payments constitutes the total performance-based payment amount for the Set of MDPP services. Although beneficiaries may currently attend at least 16 weekly sessions in months 1–6 and at least 6 monthly sessions in months 7–12, MDPP suppliers are only paid five times for beneficiary attendance: after a beneficiary attends the 1st, 4th and 9th sessions in months 1–6, and after attending the second core maintenance session in months 7–9 and in months 10–12.

Since this payment structure went into effect in 2018, we received feedback from suppliers and interested parties that the MDPP performance-based payment structure is confusing to suppliers, including those new to Medicare and existing Medicare-enrolled suppliers. Confusion with claims submission has been due in part to the MDPP payment structure, which pays for attendance and diabetes risk-reduction performance-based milestones instead of paying for an individual service. Paying for an individual service delivery is typical in Medicare. Public comments in response to the CY 2018 PFS proposed rule have indicated that CMS should modify its payment structure such that it allows for an adequate and predictable payment stream to cover the cost of providing services as long as beneficiaries attend sessions.

After 5 years of testing the current performance-based payment structure, we have determined that the attendance-based performance payments are not working. For example, there are currently five attendance-based performance payments over the 12-month MDPP service period, with a potential 4 to 5-month lag between the third payment and the fourth payment. Our monitoring data show that attendance sharply drops after the first quarter of the expanded model, which is likely after the 9th weekly session has been attended. We believe that our current payment structure does not incentivize beneficiary retention. As a result, we are proposing fee-for-service payments for beneficiary attendance, allowing for up to 22 attendance-based payments versus the five that are currently in place. Thus, we propose allowing beneficiaries to attend a maximum of 22 sessions during the core services period, including up to 16 sessions in months 1–6 and up to 6 sessions in months 7–12.

We are proposing to amend the MDPP expanded model to revise certain MDPP policies finalized in the CY 2021 PFS final rule. We are proposing to extend the flexibilities allowed under the COVID–19 Public Health Emergency for a period of 4 years until December 31, 2027. These Extended flexibilities are described in § 410.79(e)(3)(iii), and (iv) of this paragraph. The MDPP regulations provide for the following flexibilities during the PHE or an applicable 1135 waiver event:

- *Alternatives to the requirement for in-person weight measurement (§ 410.79(e)(3)(iii)).* Section 410.79(e)(3)(iii) permits an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. We stated that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale. Alternatively, the MDPP beneficiary may self-report their weight by submitting to the MDPP supplier a date-stamped photo or video recording of the beneficiary's weight, with the beneficiary visible in their home. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. This flexibility allows suppliers to bill for participants achieving weight loss performance goals.
- *Elimination of the maximum number of virtual services (§ 410.79(e)(3)(iv):* The virtual session limits described in § 410.79 (d)(2), and (d)(3)(i) and (ii) do not apply, and MDPP suppliers may provide all MDPP sessions virtually during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. MDPP suppliers were permitted to provide the Set of MDPP services virtually during the COVID–19 PHE, as long as the virtual services are furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, follow the CDC-approved National DPP curriculum requirements, and the supplier has an in-person DPRP organizational code.

We are proposing that during the Extended flexibilities period, MDPP

suppliers may provide virtual services as long as they are provided in a manner consistent with the CDC DPRP standards for distance learning. The proposed extension of these flexibilities under § 410.79(e)(3)(v) will allow beneficiaries to obtain the Set of MDPP services either in-person, through distance learning, or through a combination of in-person and distance learning for a proposed period of 4 years.

In the May 2, 2023 **Federal Register** (88 FR 27413), we published a notice extending COVID–19 PHE flexibilities for MDPP suppliers, providing them the opportunity to deliver the Set of MDPP services either virtually or in-person (or a combination of both) from May 12, 2023 through December 31, 2023. As a result, MDPP suppliers can continue delivering the Set of MDPP services on a virtual basis during this period to allow MDPP suppliers additional time to resume in-person services. For more information on the **Federal Register** Notice, please see *https://www.federalregister.gov/d/2023–09188*. For more information on the flexibilities that MDPP suppliers were permitted to implement during the PHE, please see *https://www.cms.gov/files/document/participants-medicare-diabetes-prevention-program-cms-flexibilities-fight-covid-19.pdf*.

The CDC's 2021 DPRP Standards allow two types of virtual delivery modalities: ''Distance learning'' and ''online'' delivery. According to CDC, *Distance learning* involves ''a yearlong National DPP lifestyle change program delivered 100 percent by trained Lifestyle Coaches via remote classroom or telehealth. The Lifestyle Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.'' Although ''telehealth'' is included in CDC's definition of distance learning, CMS stated in the CY 2017 PFS final rule (82 FR 52976) that MDPP services delivered via a telecommunications system or other remote technologies do not qualify as telehealth services.[242]

Additionally, CDC defines *online* delivery as a yearlong National DPP lifestyle change program delivered online for all participants. One hundred percent of the program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Lifestyle Coach teaching the content. However, live Lifestyle Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.[243]

In the CY 2021 PFS final rule (85 FR 84472),[244] we established that virtual sessions performed under flexibilities finalized in that rule could only be performed by suppliers who offered in-person services. For the proposed Extended flexibilities period, CMS proposes to limit virtual delivery to the CDC DPRP definition of ''distance learning.'' This proposal is based on the data we have obtained to date from the PHE, including anecdotal, monitoring, evaluation, claims, and CDC DPRP data, suggesting that the majority of the MDPP virtual sessions delivered during the COVID–19 PHE 1135 waiver event were distance learning sessions.

MDPP was certified and established as an in-person service. However, in response to the COVID–19 PHE, we established and implemented policies that allowed MDPP suppliers to provide MDPP services virtually during the PHE, as long as the virtual services: were furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, the curriculum furnished during the virtual sessions addressed the same curriculum topics as the CDC-approved National DPP curriculum, the supplier had an in-person DPRP organizational code, and other requirements specified at § 410.79(e)(3)(iv) were satisfied. We believe that distance learning allows for a similar live group experience for beneficiaries, but delivered only in a synchronous virtual manner through telephonic or video conference. Through utilizing distance learning, participants may still interact with their Coach and other participants in their cohort in real-time, allowing for relationship building and peer support, unlike online delivery which is delivered asynchronously. Therefore, the proposed Extended flexibilities do not include online delivery (or asynchronous virtual), as defined in the CDC DPRP Standards through the ''online'' modality, including virtual make-up sessions.

We previously stated that the MDPP expanded model was certified for expansion by the Chief Actuary of CMS, based on a model test that used in-person delivery. Given the 3-year duration of the COVID–19 PHE and the feedback received from MDPP suppliers, beneficiaries, MA plans, interested parties, and comments submitted during the CY 2022 rulemaking, there is interest in extending the flexibilities offered during the PHE to reduce the burden of traveling to an in-person class on a weekly basis, as beneficiaries experienced transportation as well as child/elder care challenges with in-person delivery. Additionally, we have heard interest in a hybrid or combination delivery option where participants could attend some in-person classes as well as virtual classes. As a result of this feedback, we are proposing to extend the flexibilities allowed under § 410.79(e)(3)(iii) (regarding use of alternative methods for obtaining weight measurements during virtual services) and § 410.79(e)(3)(iv) (regarding elimination of the maximum number of virtual services) for 4 years, to give us time to test and evaluate the distance learning delivery of MDPP.

Since MDPP was established in the CY 2017 PFS final rule, CMS and interested parties have considered whether fully virtual services could be included as part of the expanded model. For example, in the CY 2017 PFS proposed rule, CMS proposed that MDPP suppliers be allowed to provide MDPP services via remote technologies, even though the majority of CDC DPRP organizations provided in-person

[242] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 52976, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR–2017–11–15/pdf/2017–23953.pdf*.

[243] Centers for Disease Control & Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures. May 1, 2021. *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*.

[244] Centers for Medicare & Medicaid Services. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19. (85 FR 84472), December 28, 2020. *https://www.federalregister.gov/d/2020–26815*.

delivery at that time.[245] However, we also recognized that the virtual delivery of the Set of MDPP services may introduce additional risk of fraud and abuse. CMS stated that if that provision was to be finalized, we would propose specific policies in future rulemaking to mitigate these risks. In the CY 2017 PFS final rule (81 FR 80459), CMS deferred establishing policies related to organizations delivering the Set of MDPP services virtually.

In the subsequent CY 2018 PFS proposed rule, we explained our rationale for proposing not to allow fully virtual delivery of MDPP, but did propose to allow, consistent with CDC DPRP Standards, a limited number of virtual make-up sessions for participants who missed a regularly scheduled session. ''Virtual make-up session'' was defined in § 410.79(d)(2) as a make-up session that is not furnished in-person and that is furnished in a manner consistent with the requirements in paragraph § 410.79(d)(1). In the CY 2018 PFS final rule, we finalized that the Set of MDPP services would be primarily delivered in-person, in a classroom-based setting, and within an established timeline.

We prioritized establishing a service that, when delivered within this framework, would create the least risk of fraud, waste, and abuse, increase the likelihood of success for beneficiaries, and maintain the integrity of data. Furthermore, we believed at that time that in-person administration of beneficiaries' weight measurements was the most reliable and appropriate approach to monitoring beneficiary-level progress toward the 5 percent weight loss programmatic goal.

However, circumstances have changed since the start of the expanded model. We have received comments from interested parties in response to the CY 2018 PFS proposed rule and thereafter regarding increasing the limited virtual delivery of MDPP. Commenters noted that increased virtual options could expand access to MDPP for beneficiaries in rural areas, beneficiaries who are homebound or who lack transportation options, as well as increase beneficiary choice of delivery modality and flexibility of location. Commenters also noted that virtual National DPP delivery has been successful in reaching beneficiaries in certain locations. Ultimately, we finalized our policy that suppliers could offer no more than four virtual makeup sessions during months 1–6 and two virtual makeup sessions during months 7–12.

On March 13, 2020, less than 2 years after MDPP went into effect, COVID–19 was declared a national emergency by Proclamation 9994.[246] By mid-March 2020, MDPP suppliers were largely unable to deliver in-person classes due to national and local restrictions resulting from the national emergency. On April 6, 2020, CMS established MDPP PHE-related flexibilities in the first Interim Final Rule with Comment (IFC–1),[247] to allow for temporary flexibilities that prioritized availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by extreme and uncontrollable circumstances during the COVID–19 PHE. These flexibilities allowed an unlimited number of virtual sessions, waived the once-per-lifetime limit for those participating in MDPP when the PHE started, and waived the 5 percent weight loss requirement to continue with ongoing maintenance sessions.

However, we did not waive the requirement for in-person weigh-ins at that time, leaving suppliers unable to obtain the 5 percent weight loss performance payment given the local and State restrictions and stay-at-home orders during the initial months of the PHE. This prevented suppliers from collecting an in-person weight from beneficiaries at each MDPP session as described in § 424.205(g)(2)(v) to document the 5 percent weight loss.

In the CY 2021 PFS final rule, we finalized the MDPP Emergency Policy and updated the PHE flexibilities established in the IFC–1 in the following ways: allowing for virtual weigh-ins and new cohorts to begin virtually; reinstating the 5 percent weight loss requirement during an 1135 waiver event; and reinstating the once-per-lifetime limit during an 1135 waiver event starting with beneficiaries who started the Set of MDPP services in 2021 or thereafter. These changes sought to address interruptions in services caused by CMS not waiving the in-person weigh-in in IFC–1, which prevented MDPP suppliers from starting new cohorts and getting reimbursed for participants who achieved and maintained the 5 percent weight loss goals. Additionally, beneficiaries who began sessions on or before December 31, 2020, were able to re-start MDPP sessions at a later date. Similarly, we allowed suppliers to pause, then resume MDPP sessions at a later date.

During the COVID–19 PHE, we allowed full virtual delivery of MDPP. In making that policy change in the CY 2021 PFS final rule, we stated that ''Because MDPP services are covered under Medicare only when they are furnished at least in-part in-person, a supplier that does not have an organizational code authorizing in-person services (''virtual-only suppliers'') may not provide MDPP services, either virtually or in-person.'' We indicated that it is not appropriate to permit virtual-only suppliers, such as suppliers with CDC DPRP recognition in the distance learning, online, or combination only modalities, to furnish MDPP services when the Emergency Policy is in effect. This is due to the requirement that MDPP suppliers remain prepared to resume in-person delivery of the Set of MDPP services to start new cohorts and to serve beneficiaries who wish to return to in-person services when the Emergency Policy is no longer in effect.

As stated earlier, we propose to extend the flexibilities allowed during the COVID–19 PHE under § 410.79(e)(3)(iii), and (iv) for 4 years, or through December 31, 2027. We are proposing that the Extended flexibilities under § 410.79(e)(3)(iii) and (iv) continue to apply only to MDPP suppliers that have and maintain CDC DPRP in-person recognition. We recognize that organizations and interested parties may be disappointed that we are not proposing to allow organizations with CDC recognition in distance learning delivery modalities to participate in MDPP unless they also have and maintain their in-person CDC recognition. In the CY 2021 PFS final rule, we stated that virtual only suppliers are not permitted to provide the Set of MDPP services because MDPP beneficiaries may elect to return to in-person services after the PHE for COVID–19 or other applicable 1135 waiver event ends, and MDPP suppliers need to be able to accommodate their request.

[245] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. **Federal Register**, 81(136): July 15, 2016. *https://www.govinfo.gov/content/pkg/FR–2016–07–15/pdf/2016–16097.pdf.*

[246] *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/10/notice-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic-3/#:~:text=On%20March%2013%2C%202020%2C%20by,(COVID%2D19)%20pandemic.*

[247] Centers for Medicare & Medicaid Services, HHS. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. (85 FR 19230, Monday, April 6, 2020) *https://www.federalregister.gov/documents/2020/04/06/2020–06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public.*

MDPP was established as an in-person service since the original DPP test and data used in the certification were based on in-person delivery. During the COVID–19 PHE, we were able to allow greater use of virtual sessions, but the virtual delivery was primarily furnished as a virtual classroom. We are also proposing that suppliers may offer a combination delivery of MDPP, including both in-person and distance learning. We believe that after almost 4 years of having the option to deliver the Set of MDPP services through distance learning, between the COVID–19 PHE and the **Federal Register** Notice to extend the PHE flexibilities through December 31, 2023, allowing MDPP suppliers to have the option to continue delivering the Set of MDPP services in the same manner will be the least disruptive to both suppliers and beneficiaries. We are also proposing that MDPP suppliers may no longer suspend the Set of MDPP services as described in paragraph (e)(3)(v) in this section on or after January 1, 2024. We believe we have given MDPP suppliers ample time, through the **Federal Register** Notice to extend the PHE flexibilities through December 31, 2023, to adequately prepare to resume MDPP services from an operational perspective.

Furthermore, we also believe that our proposal to extend the PHE flexibilities for 4 years, or through December 31, 2027, will make MDPP more equitable and accessible for all eligible beneficiaries by providing both suppliers and beneficiaries more flexibility in how the Set of MDPP services are delivered, including in-person, distance learning, or a combination of in-person and distance learning. For an example, allowing virtual sessions will make MDPP more accessible to beneficiaries who reside in rural communities and who may have transportation and other barriers to attending in-person classes. We anticipate that the combination of a simplified payment structure in addition to more flexibilities regarding how MDPP is delivered will encourage more organizations to engage in and deliver MDPP, making MDPP more accessible to more beneficiaries.

Additionally, extending the COVID–19 PHE flexibilities for 4 years would provide CMS an opportunity to evaluate the impact of the Extended flexibilities over a longer period of time. To better track the use of distance learning through claims, we are proposing the creation of a new HCPCS G-code specific to ''distance learning,'' that will more accurately track sites from which distance learning occurs, the number of MDPP sessions delivered by distance learning, monitor the expanded model for fraud, waste, or abuse, and evaluate the impact of distance learning and in-person delivery modalities of MDPP relative to cost-savings and diabetes risk reduction among participants.

In previous rulemaking, we received comments about how to best monitor the use of virtual make-up sessions, and whether CMS would use an additional HCPCS code or modifier to indicate virtual sessions since there was a limit to the number of virtual make-up sessions a beneficiary can attend.[248] In response, we finalized the use of the virtual make-up sessions in § 410.79(d)(2) and stated that MDPP suppliers must include the virtual modifier (VM) on claims to indicate the use of the virtual make-up session. As part of the MDPP flexibilities established in response to the COVID–19 PHE, we eliminated the maximum number of virtual make-up sessions that could be delivered by MDPP suppliers, described in § 410.79(d)(2) and (d)(3)(i) and (ii), but still required MDPP suppliers to use the VM to indicate when a beneficiary received MDPP virtually.

Given the inconsistent use of the virtual modifier as it was described in the CY 2018 PFS final rule to document the virtual make-up sessions allowed during the PHE as described in § 410.79(e)(2)(iii), we propose to add a HCPCS code for distance learning to better track the synchronous virtual delivery of the Set of MDPP services to be used instead of the VM when submitting MDPP claims, including claims for make-up sessions since we are not permitting online (asynchronous virtual) delivery of the Set of MDPP services. At this time, we are not proposing to remove use of the VM entirely in-case we need it in future rulemaking, for example, should we allow online make-up sessions in future rulemaking.

MDPP supplier locations have traditionally clustered proximate to large metropolitan areas, leaving significant gaps throughout rural communities. Given that the MDPP curriculum consists of no fewer than 16 weekly sessions in months 1–6, and 6 monthly sessions in months 7–12 months, the participation commitment may pose significant challenges to beneficiaries with limited mobility or access to reliable transportation. Based on findings from the 2nd evaluation report of the MDPP expanded model,[249] we believe that in-person requirements have contributed to significant MDPP under-utilization, not only for those who reside in rural communities, but also populations that experience excessive diabetes related disparities, including populations of color, low-income beneficiaries, those living in Tribal and rural communities, and the disabled.

To date, beneficiary uptake of MDPP has been low, with 4,848 beneficiaries participating as of December 31, 2021, and approximately half of those participants were Medicare FFS beneficiaries. White women account for the majority of MDPP participants to date, with the both the National DPP and MDPP having enrolled a similar high proportion of non-Hispanic white women. RTI estimated that 97 percent of participants travel less than 25 miles to attend in-person services, with the average distance to the nearest MDPP supplier location being 5 to 7 miles.

At the time of the second annual evaluation report, which was released in November, 2022 and includes data through December 31, 2021, 39 percent of all Medicare beneficiaries live more than 25 miles from the nearest MDPP location. Extending the PHE flexibilities to allow distance learning will make MDPP more accessible to beneficiaries who live more than 25 miles from the nearest MDPP location or lack transportation.[10]

Additionally, the 2nd evaluation report (p. 32) noted that suppliers tried to make MDPP services accessible to Medicare beneficiaries by scheduling sessions at locations that were most convenient to Medicare beneficiaries. It was also noted that while beneficiary engagement and connection tend to be stronger with in-person cohorts, moving to distance learning delivery reduced participant barriers (p. 34). While some suppliers and beneficiaries experienced initial challenges migrating to fully virtual delivery, the report noted an overwhelming support from MDPP suppliers for the continued opportunity to administer MDPP through distance learning or a combination of in-person and synchronous virtual delivery. Therefore, by proposing the use of synchronous virtual delivery as an acceptable modality for MDPP delivery,

[248] Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. 82 FR 52976, November 15, 2017. *https://www.govinfo.gov/content/pkg/FR–2017–11–15/pdf/2017–23953.pdf.*

[249] RTI International. *Evaluation of the Medicare Diabetes Prevention Program: Second Evaluation Report.* November 2022. *https://innovation.cms.gov/data-and-reports/2022/mdpp-2ndannevalrpt.*

our goal is to use the Extended Flexibilities period to increase beneficiary access to and uptake of MDPP while demonstrating that the beneficiaries receiving the Set of MDPP services through distance learning experience similar or better outcomes compared to in-person delivery concerning attendance, achievement of the 5 percent weight loss goal, and cost savings.

Through the CY 2018 PFS final rule, we established important MDPP payment policies and program integrity safeguards in order to mitigate the risk of fraud, waste, and abuse in MDPP that included the creation of supplier enrollment requirements and compliance standards. MDPP monitoring activities are performed primarily through an independent monitoring contractor, with referrals sent to CMS for further investigation or enforcement action, as appropriate. We will continue to implement, adapt, and scale the current monitoring strategy for indications of fraud, waste, and abuse for both in-person and the proposed distance learning modalities. Should we identify excessive indicators of fraud, waste, and/or abuse of the synchronous virtual delivery of the Set of MDPP services during the extended PHE flexibilities period, we may opt to discontinue these flexibilities through subsequent rulemaking.

With these safeguards in-place, we anticipate the proposed programmatic updates will boost supplier enrollment, with the goal of increasing beneficiary participation and retention due to increased access to the Set of MDPP services. Moreover, we believe that extending the PHE flexibilities will especially increase equitable access to diabetes preventive services among rural and at-risk populations. For example, for beneficiaries with transportation challenges or child/elder care obligations, the ability to participate in MDPP through a live virtual classroom, or distance learning, may encourage uptake and retention among those participants. Also, for beneficiaries living in rural areas or regions with a limited number of MDPP suppliers, the distance learning option will allow beneficiaries to enroll in programs further away from their homes, making MDPP accessible to more beneficiaries. Finally, we believe that increased participation in the Set of MDPP services through distance learning may provide data necessary to conduct an impactful evaluation of the synchronous virtual delivery of MDPP.

We propose to amend § 410.79(b), (c), and (d) to remove most references to, and requirements of, the Ongoing Maintenance phase described in these sections. In the CY 2022 PFS, CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We are proposing to amend § 410.79(b), (c)(2)(i) and (e)(2), and seek comment on these proposals.

2. Proposed Changes to § 414.84

Although MDPP has over 300 suppliers representing over 1,000 locations across the US, based on fee-for-service claims analysis, only one-third of them have submitted claims since MDPP launched in April 2018. We have heard anecdotally from suppliers, CDC, and interested parties that our payment structure is complex, which has created barriers to organizations wanting to participate in MDPP. As a result, the lack of suppliers has contributed to limited beneficiary access to the preventive services offered under this expanded model. Challenges inherent in the current payment structure include irregular flow of operating funds due to the performance-based payment structure, claims denials due to the complicated payment structure, and a lack of incentive to retain participants after the 9th core session due to the potential 4 to 5-month payment lag between the 9th session attended and the 2nd session attended in months 7–9. Consistent with this last challenge, our monitoring data show a sharp drop in claims after the first quarter.

We propose to update the payment structure from a performance-based attendance and weight loss structure to a hybrid structure that pays for attendance on a fee-for-service basis and diabetes risk reduction (that is, weight loss), on a performance basis. MDPP, as defined in § 410.79(b), consists of up to 16 sessions offered during the core sessions phase (Months 1–6) and 6 monthly maintenance sessions offered during the core maintenance sessions phase (Months 7–12), (collectively the ''core sessions phase''). In the current payment structure, suppliers must submit a claim after a participant completes the first, fourth, and ninth sessions during the first 6 months, then following the second core maintenance session in months 7–9 and in months 10–12 in the core maintenance sessions phase. Depending on the timing of the ninth session attended and the second core maintenance session attended by the beneficiary in months 7 to 9, suppliers may have a 4- to 5-month gap between attendance-based performance payments in the current MDPP payment structure.

Given consistent supplier and interested party feedback regarding the complexity of this payment structure and necessary up-front costs incurred by suppliers, we propose to simplify the payment structure and pay for attendance on a fee-for-service basis. We propose creating an Attendance Payment, which we propose to define as a payment that is made to an MDPP supplier for furnishing services to an MDPP beneficiary when the MDPP beneficiary attends an MDPP core or core maintenance session. We also propose that suppliers may receive an Attendance Payment after they submit a claim for each MDPP session, starting with the first core session, using a new HCPCS G-code, *Behavioral counseling for diabetes prevention, in-person, group, 60 minutes,* or *Behavioral counseling for diabetes prevention, distance learning, 60 minutes,* for MDPP dates of service on or after January 1, 2024.

This proposed payment structure aligns closely to that of similar benefits such as the Intensive Behavioral Counseling for Obesity (IBTO) and Diabetes Self-Management Training (DSMT), and also allows suppliers to receive regular payments for service for up to a year during a 12-month MDPP service period. We propose paying for up to 22 sessions, either in-person or distance learning, or a combination of in-person and distance learning, for MDPP dates of services within a 12-month MDPP services period. In months 1 to 6, payments are allowed for one in-person or distance learning session every week up to a maximum of 16 sessions. During months 7 to 12, payments are allowed for one in-person or distance learning session every month up to a maximum 6 sessions.

We proposing to update the performance goal to mean a weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment, and removing the performance-based payments for attendance from the performance goal. We are retaining the diabetes risk-reduction performance payments, which include payments for 5 percent and 9 percent weight loss because we want to continue to pay for outcomes, and the MDPP certification includes a diabetes risk-reduction component (that is, achievement of 5 percent weight loss from baseline). Although we are proposing to remove the attendance-based performance goal and pay for attendance on a fee-for-service basis, we want to continue rewarding suppliers

for successful outcomes for beneficiaries (weight loss), and motivating them to not only retain participants, but also deliver a high-quality program that achieves better outcomes.

As part of the performance payments, MDPP suppliers must still submit a claim when 5 percent weight loss from baseline weight is achieved and will receive a one-time payment for this claim (weight loss G-code). We are proposing to create a new HCPCS G-code, ''Maintenance of 5 percent weight loss from baseline, months 7–12'' to be submitted along with the monthly session claim for beneficiaries who have met the 5 percent weight loss performance goal, for whom the one-time claim for 5 percent weight loss has been submitted. This maintenance of 5 percent weight loss code replaces the attendance plus 5 percent weight loss HCPCS G-codes, G9878 and G9879, in months 7–12.

The one-time claim for 5 percent weight loss must be submitted prior to submitting a claim for the enhanced payment in months 7 to 12 for maintaining the 5 percent weight loss. Additionally, suppliers must continue to submit a claim when 9 percent weight loss from baseline weight is achieved per § 414.84(b)(7), so they may receive a one-time payment for this claim.

This proposed payment structure increases the maximum attendance-based payments a supplier may receive in the first 6 months by $56 per MDPP beneficiary, while allowing for similar maximum attendance payments in months 7–12 and maintaining the maximum total payment of $768 per person during the MDPP services period. Also, this proposed payment structure takes into consideration the Extended flexibilities, by adding a distance learning HCPCS G-code. The new structure simplifies the claims submission process because it no longer requires that suppliers submit 11 to 15 G-codes for different attendance-based sessions at irregular intervals.

This proposed payment structure allows suppliers to submit one of two G-codes (depending on whether the MDPP session was delivered in person or via distance learning) for each session. In months 7–12, suppliers may also add the proposed maintenance of the 5 percent weight loss from baseline G-code to their claim once the 5 percent weight loss has been achieved. The proposed payment structure allows suppliers to indicate which sessions were held via distance learning without needing to provide additional information in the claim submission process. The proposed new payment structure reduces complexity by reducing the number of G-codes from 15 to 6.

Table 41 displays the proposed MDPP payment structure and Table 42 indicates the current CY 2023 performance payments.

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TABLE 41: Proposed Changes to MDPP Payment Structure to include Attendance-Based Service Payments and Diabetes Risk Reduction Performance Payments

HCPCS G-Code	Payment Description*	CY 2024
GXXX0	Behavioral counseling for diabetes prevention, in-person, group, 60 minutes	$25
GXXX1	Behavioral counseling for diabetes prevention, distance learning, 60 minutes	$25
G9880	5 percent WL Achieved from baseline weight	$145
GXXX2**	Maintenance 5 percent WL from baseline in months 7-12	$8
G9881	9 percent WL Achieved from baseline weight	$25
G9890	Bridge Payment	$25
Subtotal Maximum Attendance-Based Payment		**$550**
Total Maximum Payment		**$768**

**Medicare pays up to 22 sessions billed with codes GXXX1 and GXXX0, combined, in a 12-month period:*
Months 1-6: 1 in-person or distance learning session every week (max 16 sessions)
Months 7-12: 1 in-person or distance learning session every month (max 6 sessions)
*** Suppliers must submit claim for 5 percent weight loss (G9880) prior to submitting claims for the maintenance 5 percent WL from baseline in months 7-12.*

TABLE 42: CY 2023 MDPP Payment Structure

HCPCS G-Code	Payment Description	CY 2023
	Core Sessions (Months 1-6)	
G9873	Attend 1 Core Session	$38
G9874	Attend 4 Core Sessions	$115
G9875	Attend 9 Core Sessions	$191
	Core Maintenance (CM) Sessions (Months 7-12)	
G9876	Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	$76
G9877	Attend 2 Core Maintenance Sessions (No 5 percent WL) in CM Interval 2 (Months 10-12)	$76
G9878	Attend 2 Core Maintenance Sessions (5 percent WL) in CM Interval 1 (Months 7-9)	$101
G9879	Attend 2 Core Maintenance Sessions (5 percent WL) in CM Interval 2 (Months 10-12)	$101
G9880	5 percent WL Achieved from baseline weight	$184
G9881	9 percent WL Achieved from baseline weight	$38
G9890	Bridge Payment	$38
G9891	Non-payable session code (This code is for reporting purposes only).	$0
	Core Maintenance Sessions (Months 7-12)**	
G9882	Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)	$57
G9883	Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)	$57
G9884	Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)	$58
G9885	Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months (22-24)	$58
Subtotal Maximum Attendance-Based Payment		**$496**
Total Maximum Payment		**$768**

**In the CY 2022 PFS, CMS removed the Ongoing Maintenance Sessions for those beneficiaries who started MDPP services on or after January 1, 2022. MDPP beneficiaries who were participating in the Set of MDPP Services on or before December 31, 2021 may continue with the ongoing maintenance phase if they maintain 5 percent weight loss and attendance requirements.

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In previous rulemaking, we received comments regarding how to best monitor the use of virtual make-up sessions, and whether we would use an additional HCPCS code or modifier to indicate virtual sessions since there is a limit to the number of virtual make-up sessions a beneficiary can attend. In response, we finalized the use of the virtual make-up sessions in § 410.79(d)(2) and stated in the preamble to the CY 2018 PFS final rule that MDPP suppliers must include the virtual modifier on claims to indicate the use of the virtual make-up session. As part of the flexibilities established in response to the COVID–19 PHE, we eliminated the maximum number of virtual make-up sessions that could be delivered by MDPP suppliers, described in § 410.79(d)(2) and (d)(3)(i) and (ii), but still required MDPP suppliers to use the virtual modifier to indicate when a beneficiary received MDPP virtually.

We are proposing to amend § 414.84(a), (b), (c), and newly redesignated paragraphs (d)(1) and (e). We seek comment on these proposals.

3. Changes to § 424.205 (a), (b)(1), (c), and Newly Designated (c)(1), (d)(14), (f)(2)(i), (g)(1)(i)(C)

The Centers for Disease Control and Prevention (CDC), which administers the Diabetes Prevention Recognition Program (DPRP), is responsible for implementing the quality assurance function of the National DPP at the national level, including for MDPP. The DPRP awards four categories of recognition: Pending, preliminary, full, and full-plus. Organizations may participate in MDPP with preliminary, full, or full-plus CDC recognition. Organizations may advance in CDC DPRP recognition by demonstrating their ability to effectively deliver the behavioral change program (preliminary) and achieve the outcomes shown to prevent or delay type 2 diabetes (full and full-plus). To achieve full CDC recognition, organizations must demonstrate a reduction in risk of developing type 2 diabetes among completers in the evaluation cohort by showing that at least 60 percent of all completers achieved at least one of the following outcomes:

- At least 5 percent weight loss 12 months after the cohort began; or
- At least 4 percent weight loss and at least 150 minutes/week on average of physical activity 12 months after the cohort began; or
- At least a 0.2 percent reduction in HbA1C.

Organizations are granted an additional 2 years of full recognition (full-plus), for a total of 5 years if, at the time full recognition is achieved, organizations meet the following retention criteria:

- A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions;
- A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and
- A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

In the CY 2017 PFS final rule, we indicated that we would align the CDC's DPRP and MDPP to the greatest extent possible. When the CY 2018 PFS went into effect on January 1, 2018, CDC's 2018 DPRP Standards had neither been publicly released nor gone into effect. For these reasons, we had to establish an interim MDPP preliminary recognition so that eligible organizations could begin enrolling in Medicare to

become MDPP suppliers starting January 1, 2018, and approved suppliers could start serving Medicare beneficiaries on April 1, 2018.

When the CY 2018 PFS final rule was issued, the CDC 2015 DPRP Standards were still in effect, and CDC only recognized organizations with pending or full DPRP recognition. Consequently, CMS and CDC developed an interim solution that would allow organizations that met the MDPP interim preliminary recognition standard, which went into effect on January 1, 2018, to become eligible to enroll in Medicare as an MDPP supplier.

Because CMS and CDC understood that there would be a 2 to 4-month gap between when the CY 2018 PFS went into effect for MDPP (January 1, 2018) and when the CDC 2018 DPRP Standards would be cleared and go into effect, we worked with CDC to establish an interim solution so that eligible organizations with MDPP interim preliminary or CDC DPRP full recognition could apply to Medicare to become MDPP suppliers before the CDC's 2018 Standards went into effect on March 1, 2018. The CY 2018 PFS final rule at § 424.205(c)(2)(ii) established that CDC-recognized organizations with pending CDC DPRP recognition could meet additional criteria for an ''interim preliminary recognition'' standard and enroll as MDPP suppliers. With the MDPP new supplier type going into effect on January 1, 2018, and beneficiary enrollment starting on April 1, 2018, we wanted suppliers to be able to enroll in Medicare to become MDPP suppliers in time for the April 1 MDPP launch.

Now that the CDC DPRP Standards for preliminary recognition are in effect, we propose to remove § 424.205(c) and retire the MDPP ''interim preliminary recognition'' standard. We also propose to amend § 424.59(a)(1) (redesignated § 424.205(b)(1)) to require that, at the time of enrollment, organizations have preliminary, full, or full-plus CDC DPRP recognition. As described in the CY 2018 PFS final rule, MDPP suppliers who received MDPP interim preliminary recognition during the 4-month time period between when the CY 2018 PFS final rule was published and when the CDC 2018 standards went into effect, have achieved at least CDC preliminary recognition.

To maintain compliance with the current CDC DPRP Standards, organizations that enrolled in Medicare as MDPP suppliers based on their MDPP interim preliminary recognition between January 1, 2018 and February 28, 2018 would have had at least two CDC DPRP evaluations given the 5-year time lapse. Per CDC DPRP Standards, organizations are required to submit data to CDC every 6 months, and undergo evaluation every 12 to 18 months, depending upon the timing of new cohorts.

Since the CDC DPRP Standards were updated in 2018 and 2021 and are due to be updated in Spring 2024, suppliers are required to meet the most current CDC DPRP Standards for preliminary, full, or full-plus recognition to maintain their eligibility to enroll and participate in MDPP as MDPP suppliers. Organizations that are interested in enrolling in Medicare as MDPP suppliers should refer to the CDC DPRP's most current standards [1] to understand how to obtain preliminary, full, or full-plus CDC recognition, and consult § 424.205 for all other enrollment conditions that need to be met, in advance of submitting their application to become a MDPP supplier.

We propose to amend § 424.205 newly designated paragraphs (c) and (f) to remove reference to, and requirements of, the Ongoing Maintenance phase described in these sections with the exception of § 424.205 newly designated paragraph (d)(14), which we are retaining for historical recordkeeping and crosswalk purposes. In the CY 2022 PFS, CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We are proposing to amend § 424.205 (a), (b)(1), newly redesignated paragraphs (c)(1) and (g)(1)(i)(C). We seek comment on these proposals.

4. Proposed Changes to § 424.210(b) and (d)

We propose to amend § 424.210(b) and (d) to remove reference to, and requirements of, the Ongoing Maintenance phase described in these sections. In the CY 2022 PFS final rule, CMS removed eligibility for the Ongoing Maintenance Sessions for those beneficiaries who started the Set of MDPP Services on or after January 1, 2022. Eligibility for these services will end December 31, 2023.

We are proposing to amend its regulation at § 424.210 by amending paragraphs (b) and (d). We seek comment on these proposals.

J. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 1834(q) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA), directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Since the bill was passed, we have taken steps to implement this program and codified the AUC program in our regulations at 42 CFR 414.94. In CY 2020, we began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information and the program currently operates in this phase.

1. Background

AUC are evidence-based guidelines that assist clinicians in selecting the imaging studies most likely to improve health outcomes for patients based on their individual clinical presentation. AUC present information in a manner that links a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). For purposes of this program, AUC are a set or library of individual AUC. Each individual criterion is an evidence-based guideline for a particular clinical scenario based on a patient presenting symptoms or condition. Under this program, any clinician who orders an advanced diagnostic imaging service must consult AUC for the imaging service ordered. Examples of advanced diagnostic imaging services include computed tomography, positron emission tomography, nuclear medicine and magnetic resonance imaging.

To consult AUC, clinicians use clinical decision support mechanisms (CDSMs). CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information, but may be more effective when they are integrated into electronic health records (EHRs). Ideally, clinicians would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

Under the AUC program, clinicians and facilities that furnish the imaging service are responsible for reporting information about the ordering clinician's AUC consultation on the imaging service claim. The furnishing clinician and facility are not paid if the ordering clinician fails to consult and/or if the consultation information is not correctly included on the imaging service claim.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria

for Certain Imaging Services,'' which directed the Secretary to establish a program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional's consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements and Implementation

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals (based on low adherence to AUC) for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). These four components are precursors to the requirement that, beginning for CY 2017, we establish mandatory prior authorization procedures for outlier ordering professionals when ordering advanced diagnostic imaging services (section 1834(q)(6) of the Act).

a. Establishment of AUC

We addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act, establishment of AUC, in the CY 2016 PFS final rule with comment period (80 FR 70886). With this rule, we began to codify the statutory requirements in our regulations at 42 CFR 414.94. We also defined provider-led entity (PLE) as well as additional definitions under section 1834(q)(1) of the Act in our regulations at § 414.94(b). In § 414.94(c)(1) and (2), respectively, we set forth the requirements and process by which PLEs become qualified by CMS to develop, modify or endorse AUC. We qualified the first group of PLEs under the AUC program and posted them to the CMS website in June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act.

b. Identification of Mechanisms for Consultation With AUC

We addressed the second component under section 1834(q)(3) of the Act, identification of mechanisms for consultation with AUC, in the CY 2017 PFS final rule (81 FR 80170). In this rule we defined clinical decision support mechanism (CDSM) in § 414.94(b). In § 414.94(g)(1) and (2), respectively, we set forth the requirements CDSMs must meet and established a process by which CDSMs may become qualified by CMS in accordance with the statutory requirements under section 1834(q)(3)(B)(ii). We qualified the first group of CDSMs under the AUC program and posted them to the CMS website in July 2017.

c. AUC Consultation and Reporting

We addressed the third component under section 1834(q)(4) of the Act, AUC consultation by ordering professionals, and reporting on AUC consultation, primarily in the CY 2018 PFS final rule (82 FR 53190). Additionally, in the CY 2017 PFS final rule, we defined terms in § 414.94(b) (81 FR 80405 and 80406) and identified exceptions to the AUC consultation and reporting requirements under section 1834(q)(4) in § 414.94(i) (81 FR 80422 through 80424) which are pertinent to the third component. We also continued to revise the regulation at § 414.94 as needed and in response to comments from interested parties in subsequent rulemaking cycles. These updates, revisions and clarifications, which continued through annual PFS rulemaking for CYs 2018, 2019, and 2020, are discussed throughout this section as they directly relate to the AUC consultation requirement under section 1834(q)(4)(A) of the Act and reporting requirement under section 1834(q)(4)(B) of the Act.

In the CY 2017 PFS final rule we defined applicable payment systems consistent with section 1834(q)(4)(D) of the Act to include the PFS established under section 1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment system under section 1833(i) of the Act (81 FR 80406). In the CY 2016 PFS final rule with comment period we defined applicable setting consistent with section 1834(q)(1)(D) of the Act to include a physician's office, a hospital outpatient department (including an emergency department), and an ambulatory surgical center (80 FR 71105). We later added independent diagnostic testing facility (IDTF) to the definition of applicable setting in the CY 2019 PFS final rule (83 FR 59690 and 59691).

Also in the CY 2017 PFS final rule, consistent with section 1834(q)(4)(C) of the Act, we identified exceptions to the AUC consultation and reporting requirements under section 1834(q)(4) of the Act in the case of: a service ordered for an individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship (81 FR 80422 through 80424). The significant hardship exception criteria and process under § 414.94(i)(3) was later updated in the CY 2019 PFS final rule (83 FR 59697 through 59700).

In the CY 2018 PFS final rule, we established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who were ready to participate in the AUC program could consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals (82 FR 53193 through 53195). Furnishing professionals who were ready to do so could report AUC consultation information on the claim. To incentivize early use of qualified CDSMs for consulting AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

In addition, in the CY 2018 PFS final rule, we established the start date of January 1, 2020, for the Medicare AUC program for advanced diagnostic imaging services in § 414.94(j)(1) (82 FR 53189 through 53195). Specifically, for services ordered on and after January 1, 2020, we established that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services in § 414.94(j), and furnishing professionals must report AUC consultation information on the Medicare claim in § 414.94(k). In the CY 2019 PFS final rule, we specified under § 414.94(j)(2) that when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC

consultation with a qualified CDSM. In the CY 2018 PFS final rule, we further specified that the AUC program, including the claims denial payment penalty phase, would begin on January 1, 2020, with a year-long educational and operations testing period for CY 2019 during which AUC consultation information was expected to be reported on claims, but claims would not be denied for failure to include proper AUC consultation information (82 FR 53193 through 53195). As discussed in further detail below, the educational and operations testing period was subsequently extended multiple times and the program currently operates in the educational and operations testing period.

In the CY 2018 PFS final rule and consistent with section 1834(q)(4)(B) of the Act, we established in § 414.94(k) that the following information must be reported on Medicare claims for advanced diagnostic imaging services: (1) the qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional) (82 FR 53190 through 53193). Section 1834(q)(4)(B) of the Act specifies that payment for advanced diagnostic imaging service claims under the AUC program may only be made if the claim submitted by the furnishing professional (of which there can be more than one if the professional component is furnished by a different entity than the technical component) includes this information about the ordering professional's AUC consultation. This statutory requirement establishes a real-time claims-based reporting requirement whereby payment for the imaging service is contingent upon specific information being present on the claim. We worked to operationalize the real-time claims-based reporting requirement by announcing our intention to use G-codes and HCPCS modifiers to report AUC consultation information on the Medicare claims in the CY 2019 PFS final rule.

In the CY 2022 PFS final rule (86 FR 64996), we provided further clarification around the scope of the AUC program specifically pertaining to updates or modifications to orders for advanced diagnostic imaging services (86 FR 65227 through 65229), the extreme and uncontrollable circumstances significant hardship exception (86 FR 65229 and 65230) and specified claims processing solutions, including creation and use of a new HCPCS modifier intended to accurately identify claims that are and are not subject to the AUC program requirements. We also discussed special circumstances related to: services furnished by a critical access hospital (CAH) (86 FR 65231 and 65232), services paid under the Maryland Total Cost of Care Model (86 FR 65232 and 65233), inpatients converted to outpatients (86 FR 65233 and 65234), Medicare as the secondary payer (86 FR 65234 and 65235), and imaging services ordered prior to the start of the claims denial payment penalty phase but furnished on or after the start of the payment penalty phase (86 FR 65235). We addressed where to identify the ordering professional on practitioner claims for imaging services (86 FR 65231) (we addressed where to identify ordering professionals on institutional claims in educational materials following the CY 2019 PFS final rule claims-based reporting discussion (83 FR 59696)) and confirmed that claims that do not properly append AUC consultation information will be returned for correction and resubmission, rather than denied, when the payment penalty phase begins (86 FR 65234). We did not specify how long claims would be returned before the payment penalty phase would shift to claim denials. Finally, we established that the payment penalty phase would begin on the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19. Under this specification and with the declared end of the PHE for COVID–19 on May 11, 2023, the payment penalty phase would have been scheduled to begin on January 1, 2024. However, as announced via the AUC website in 2022 and discussed further below in this section of the proposed rule, the educational and operations testing period will continue until further notice. We did not include provisions pertaining to the AUC program in the CY 2023 PFS final rule (87 FR 69404).

d. Identification of Outlier Ordering Professionals

We began to address the fourth component under section 1834(q)(5) of the Act, identification of outlier ordering professionals, in the CY 2017 PFS final rule by finalizing the first list of priority clinical areas (PCAs) in § 414.94(e)(5) (81 FR 80406 through 80412) which were intended to ultimately guide identification of outlier ordering professionals who would eventually be subject to prior authorization when ordering advanced diagnostic imaging services. Section 1834(q)(5) of the Act directs CMS to: (1) determine on an annual basis no more than 5 percent of total ordering professionals who are outlier ordering professionals; and (2) base the determination of an outlier ordering professional on low adherence to AUC which may be based on comparisons to other ordering professionals and include data for ordering professionals for whom prior authorization applies; and (3) use 2 years of data to identify outlier ordering professionals; and (4) consult with physicians, practitioners and other interested parties in developing methods to identify outlier ordering professionals. To date, we have not proposed or codified the methods for identifying outlier ordering professionals as prescribed by section 1834(q)(5) of the Act, and thus, we have not subjected any ordering professionals to prior authorization when ordering advanced diagnostic imaging services as prescribed by section 1834(q)(6) of the Act.

4. Timeline

As evident from the description of our regulatory activities to date, we have not met the statutory implementation time frame for the AUC program components. The educational and operations testing period began January 1, 2020, and the AUC program continues to operate in this phase currently. In this phase, there are no payment penalties for advanced diagnostic imaging service claims that do not append AUC consultation information. The provisions in section 1834(q) of the Act repeatedly stress the importance of engagement with interested parties in developing the Medicare AUC program. Throughout our implementation activities, we have intentionally taken a diligent, stepwise implementation approach to maximize the opportunity for public comment and engagement with interested parties, and allow for adequate advance notice to physicians and practitioners, beneficiaries and other AUC interested parties of any programmatic changes or updates. These efforts to maximize engagement included speaking and answering live questions at multiple CMS Open Door Forums, participating in external meetings sponsored by and at the request of interested parties like medical specialty societies and health care practitioners, and meeting in person and virtually with interested parties upon request to receive feedback and answer questions to the best of our ability and within the context of already publicly available information. All of these interactions were critical to inform our proposals during each round of notice and comment rulemaking. This

approach has allowed us to be comprehensive in our assessment of implementation options and regulatory proposals, responsive to concerns expressed by interested parties, and agile in reacting to unexpected events, like the PHE for COVID–19. Since the CY 2022 PFS final rule was released, we have used the AUC website [250] to publicly announce updates to the AUC program. In July 2022, we updated the AUC website to inform interested parties that the payment penalty phase of the AUC program would not begin on January 1, 2023 even if the PHE for COVID–19 ended in 2022. This update also stated that the educational and operations testing period would continue and that we are not able to forecast when the payment penalty phase will begin. In October 2022, we updated the AUC website again to announce that applications for CDSM and PLE initial qualification and re-qualification would not be accepted for the 2023 application cycle and that all CDSMs and PLEs qualified as of July 2022 would remain qualified through this cycle.

5. Proposal To Pause Program for Reevaluation

Since 2015, we have taken a thoughtful, stepwise approach that maximized engagement and involvement of interested parties to implement the statutory provisions set forth in section 1834(q), as added by section 218(b) of the PAMA, using notice and comment rulemaking. As discussed previously in this section of the proposed rule, we established the first two components of the AUC statutory requirements—establishment of AUC and mechanisms for consultation. We began to build the parameters for the fourth component, outlier identification, leading to prior authorization, by establishing the PCAs. And we began implementing the third component, the AUC consultation and reporting requirement, using the ongoing educational and operations testing period. At this time, however, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we propose to pause implementation of the AUC program for reevaluation, and rescind the current AUC program regulations from § 414.94. We expect this to be a hard pause to facilitate thorough program reevaluation and, as such, we are not proposing a time frame within which implementation efforts may recommence.

a. Real-Time Claims-Based Reporting

Section 1834(q)(4)(A) of the Act requires ordering professionals to consult AUC using a qualified CDSM. Section 1834(q)(4)(B) of the Act requires furnishing professionals to report information about the ordering professional's AUC consultation with a qualified CDSM on the Medicare claim for the advanced diagnostic imaging service the ordering professional ordered. This section dictates that payment to the furnishing professional is contingent on reporting the ordering professional's AUC consultation information, which must include the ordering professional's NPI, the qualified CDSM that was consulted, and whether the service ordered adheres or does not adhere to the AUC consulted, or if there were no AUC applicable to the order available for consultation via the qualified CDSM that was consulted as described above.

While each component of the statutory requirements has presented unique challenges to implement, the greatest challenge has been in fully implementing and operationalizing the real-time claims-based reporting requirement consistent with section 1834(q)(4)(B) of the Act so as to ensure accurate reporting, claims processing and, ultimately, outlier identification and prior authorization. We formally solicited public comment and feedback from interested parties in notice and comment rulemaking in the CY 2017 PFS rulemaking cycle, and have welcomed and encouraged feedback and information from interested parties less formally throughout the duration of our implementation efforts in each successive year. In the CY 2017 PFS final rule, we discussed the importance of developing and operationalizing a meaningful solution for collecting AUC consultation information on Medicare claims. We explained that ''we must diligently evaluate our options taking into account the vast number of claims impacted and the limitations of the legacy claims processing system.'' We further noted that ''[m]oving too quickly to satisfy the reporting requirement could inadvertently result in technical and operational problems that could cause delays in payments'' (81 FR 80420). In addition to consulting with claims processing experts outside of and between rulemaking cycles, we continued to clearly and intentionally solicit feedback and suggestions from interested parties to assist us in developing workable claims processing edits and solutions to operationalize the AUC reporting requirement consistent with section 1834(q)(4)(B) of the Act in rulemaking cycles for the CY 2018, 2019 and 2022 PFS.

Having considered many rounds of input from interested parties, including internal and external experts, and diligent exploration of options, we have come to believe that the real-time claims-based reporting requirement prescribed by section 1834(q)(4)(B) of the Act presents an insurmountable barrier for CMS to fully operationalize the AUC program. To properly apply the statutory provisions of the AUC program, including specifications around settings in which services are furnished and payment systems under which Medicare payments are made, it is critical that claims are accurately identified in the Medicare claims processing system and accurately subjected to system's edits to ensure AUC consultation information is properly reported on the claim. Equally important is ensuring that claims not subject to the AUC program are not inappropriately subjected to claims system's edits. We consider a process where the Medicare claims processing system properly and accurately identifies only claims for services subject to the AUC program requirements, without manual action by practitioners/facilities that submit claims, to be a fully automated process. The existing Medicare claims processing system does not have the capacity to fully automate the process for distinguishing between advanced diagnostic imaging claims that are or are not subject to the AUC program requirement to report AUC consultation information as prescribed by section 1834(q)(4)(B) of the Act. This means that the Medicare claims processing system is not able to ensure that claims for services that are not subject to the AUC consultation information reporting requirement will not be improperly denied for failure to append AUC consultation information. We note here that our intention, as announced in the CY 2022 PFS final rule, was to begin the payment penalty phase of the AUC program by returning, rather than denying, claims for advanced diagnostic imaging services that do not contain AUC consultation information for correction and resubmission; however, section 1834(q)(4)(B) of the Act specifies

[250] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program.*

that payment for advanced diagnostic imaging services under the AUC program may only be made if the claim for the imaging service includes specific AUC consultation information. Consequently, the payment penalty phase would eventually need to shift from returning claims for correction and resubmission to denying claims. As such, and without the practicable capacity to fully automate the process for editing claims to ensure only appropriate claims are edited for AUC consultation information, there is a significant risk that full implementation of the penalty phase of the AUC program would result in inappropriate claims denials.

To avoid these inappropriate denials, we considered requiring claims to include certain modifiers that would identify them as not being subject to the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act. However, this would add an extra layer of burden on furnishing professionals, including freestanding and hospital-based imaging facilities, requiring them to append information to the claims even for services that are not subject to the AUC consultation and reporting requirement in order to allow us to identify which imaging services are and are not subject to the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act, and allow us to appropriately process claims.

Additionally, the AUC program is designed to target a subset of advanced diagnostic imaging services furnished in specific settings and paid under specific payment systems, as opposed to, for example, all Medicare part B advanced diagnostic imaging service claims, and includes multifaceted criteria for identifying which services are subject to the program. As such, ordering professionals would need to know, at the time of the order, where each imaging service will be furnished and under which payment system the claim will be paid to determine whether AUC consultation, and transmission of AUC consultation information with the order, is required. Furnishing professionals, including freestanding and hospital-based imaging facilities, would need to be able to delineate which orders received without AUC consultation information are not subject to the AUC program from those that are subject to the program and its requirements. If they are able to confirm that a service is not subject to the AUC program, then they would need to identify the appropriate modifier to append to the claim so it can be processed and be paid without AUC consultation information. Alternatively, if they find that the order is subject to the AUC program, they would need to take steps to obtain AUC consultation information from the ordering professional, decline to furnish the service, or risk denial of the claim for a furnished service.

An example that highlights the practical complexity and unwieldiness of the AUC program is the, not uncommon, scenario where an advanced diagnostic imaging service is furnished in two settings—only one of which is an applicable setting. For example, this occurs when the technical component (TC) of an imaging service is furnished in a setting, like a critical access hospital (CAH), that is not an applicable setting. As we discussed in the CY 2022 PFS final rule, because the service was not furnished in an applicable setting, the entirety of the service (both the technical and professional component (PC)), is not subject to the AUC consultation requirement. Therefore, neither of the separate claims for the TC and PC for the service are required to include AUC consultation information. However, there is no way in real-time claims processing for us to identify that the PC claim is for an imaging service that was not furnished in an applicable setting. For the claim to process and be paid when it does not include AUC consultation information, the furnishing professional for the PC would need to append a modifier to the claim to identify it as not being subject to the AUC consultation and reporting requirement.

b. Accuracy of Claims Data

Because, as noted above, the CMS claims processing system is unable to fully automate editing advanced diagnostic imaging claims, risks around reporting accuracy are inherent to the AUC program prescribed by section 1834(q)(4)(B) of the Act. These risks directly impact furnishing professionals, including free-standing and hospital-based facilities, by affecting payment for advanced diagnostic imaging services they furnish, in some cases based on conduct of ordering professionals with whom they have little or no affiliation. Beyond the potential for inappropriate claims denials as discussed above, by manually appending information to their claims as supplied by ordering professionals, furnishing professionals are attesting to the credibility and accuracy of that information and may find themselves subject to audits or post-pay review. Considering that the AUC program ultimately involved the identification of outlier ordering professionals and imposing a prior authorization procedure for them as prescribed in sections 1834(q)(5) and (6) of the Act, reliance on manual reporting by one party of information supplied by another party presents a serious risk to data accuracy and integrity. Since section 1834(q)(5) of the Act directs CMS to use these data from claims-based AUC consultation information collection to identify outlier ordering professionals, and section 1834(q)(6) of the Act directs CMS to require prior authorization for outlier ordering professionals, the quality and accuracy of the data used to make these determinations is critical to ensure the AUC program leads to appropriate application of prior authorization for advanced diagnostic imaging services.

c. Effect on Medicare Beneficiaries

We recognize that a program to promote the use of AUC for advanced diagnostic imaging could improve imaging utilization patterns for Medicare beneficiaries. Ideally, beneficiaries would undergo fewer and more appropriate imaging procedures to inform more efficient treatment plans and address medical conditions more quickly and without unnecessary tests. In the CY 2019 PFS final rule, we estimated how adding AUC consultation to an ordering professional's workload would directly impact a Medicare beneficiary based on the additional office visit time needed for consultation and ordering. We estimated this impact by calculating the cost to beneficiaries associated with the additional consultation time to be $68,001,000 annually (83 FR 60040). In the CY 2022 PFS final rule we updated this estimate based on Medicare claims data and changes in wage estimates to $54,789,518 annually. We estimated that potential savings would offset this cost by $27,394,759 annually based on process efficiencies that may be implemented over time by ordering professionals (86 FR 65626). In the CY 2019 PFS final rule, we estimated other impacts associated with the AUC program including potential savings to the Medicare program. We estimated potential savings of $700,000,000 annually by extrapolating savings from a clinical decision support pilot project performed by the Institute for Clinical Systems Improvement in Bloomington, Minnesota [251] (83 FR 60043). Since this estimate was based on information from previous clinical decision support experiences and not Medicare claims

[251] Miliard, M. Nuance, ICSI aim to prevent unnecessary imaging tests. Healthcare IT News. November 10, 2010.

data or wage estimates, we did not update this estimate in the CY 2022 PFS final rule.

While the incorporation of any new process into workflows can be expected to impart burden that eventually lessens, we have additional concerns about risks for beneficiaries stemming from the real-time claims-based reporting requirement prescribed by section 1834(q)(4)(B) of the Act. Beyond the burden of adding to the workload of the ordering and furnishing professionals for advanced diagnostic imaging services, the AUC consultation program can produce risk to beneficiaries in receiving timely imaging services, and potentially being financially liable for advanced diagnostic imaging service claims denied by the Medicare program, whether properly or due to omissions or errors in conveying AUC consultation information on claims. Beneficiaries may experience delays in scheduling and receiving imaging if AUC information is not properly provided with the order from the ordering professional to furnishing professionals/facilities. This may happen, even if the imaging service is not subject to the AUC program requirements, in any circumstance where the furnishing professional/facility is unclear whether the AUC consultation and reporting requirements apply (for example if Medicare is the secondary payer, or under other circumstances as discussed in the CY 2022 PFS final rule). Section 1834(q) of the Act does not separately establish protections to Medicare beneficiaries from financial liability for advanced diagnostic imaging service claims not paid by Medicare as required under the AUC program. As discussed above, because the Medicare claims processing system cannot fully automate a process to ensure only claims for advanced diagnostic imaging services subject to the AUC program reporting requirement under section 1834(q)(4)(B) of the Act are edited as such, there is a risk of inappropriate claims denials. Additionally, in the event that an ordering professional fails to consult AUC or neglects to communicate AUC consultation information (or relevant exception information) to the furnishing professional/facility and the furnishing professional/facility proceeds with furnishing the imaging service despite the absence of this information, the beneficiary may incur unwarranted financial liability for the imaging service.

d. Summary

Taken together and, in particular, due to the inability of the Medicare claims processing system to automate claims processing edits that ensure only claims subject to the AUC program requirements as prescribed in section 1834(q) of the Act will be processed as such, returned or denied accordingly, we believe the inherent risks in terms of data integrity and accuracy, beneficiary access, and potential beneficiary financial liability for advanced diagnostic imaging services render the AUC program impracticable, and have led us to our proposal to pause efforts to implement the AUC program for reevaluation and rescind current regulations. Working within the parameters prescribed under section 1834(q) of the Act, we have not identified any practical way to move the AUC program forward beyond the educational and operations testing period. Further, without a way forward to fully implement the AUC program, we believe there is no utility in continuing the educational and operations testing period. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking. We note, and discuss further below in this section of the proposed rule, that clinical decision support tools can be beneficial in assisting with clinical decision making and we encourage continued use of clinical decision support in a manner that best serves and assists clinicians.

6. Summary of Other Quality Initiatives

As discussed above, section 218(b) of the PAMA of 2014 entitled ''Promoting Evidence-Based Care'' established the Medicare AUC program. The statute was designed to promote the use of AUC for advanced diagnostic imaging services with enforcement through immediate non-payment of claims for which there was no AUC consultation and, eventually, prior authorization for ''outliers'' that more frequently neglect to consult AUC. Promoting the use of AUC in clinical practice is an activity that encourages the use of evidence-based information/guidelines/recommendations to guide patient care thus resulting in improved value and quality. Subsequent to PAMA, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program, which is an incentive program to tie Medicare PFS payment to performance by rewarding high-value, high-quality care. After enactment of these laws, CMS worked to implement both programs by successfully establishing and fully operationalizing the Quality Payment Program (both the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)) and, as discussed above, taking steps to implement each component of the AUC program up to and through the ongoing educational and operations testing period. We have developed outreach and educational materials and made all AUC program-related information available on the CMS AUC website.[252] We believe that many goals of the AUC program have been met by the QPP and other more comprehensive accountable care initiatives such as the Medicare Shared Savings Program, advances in electronic clinical quality measures (eCQMs) and Interoperability requirements of Certified Electronic Health Record Technology (CEHRT), and new Innovation Center models such as ACO REACH and Kidney Care Choices where physicians and other health care providers join together to take responsibility for both the quality of care and total cost of care their patients experience. These quality and value-based care programs are designed to achieve quality of care goals by addressing issues of utilization, cost and quality holistically instead of via claim-by-claim examination and improvement initiatives for specific types of services.

While these initiatives, including the Shared Savings Program, do not specifically target advanced diagnostic imaging, we expect that this more global approach to improving quality and accountable care would broadly affect all services, including advanced diagnostic imaging utilization. Both ACO participation and episode of care payment models promote accountability for beneficiary cost of care as well as improving or maintaining quality of care according to applicable quality measures. Similarly, the MIPS ties together quality and costs by measuring and scoring performance in four performance categories: quality, cost, improvement activities, and promoting interoperability. MIPS uses measures and activities in each of these categories, such as the Total Per Capita Cost (TPCC) specialty measure, which focuses on effective primary care management to support Medicare savings. While also not specific to advanced diagnostic imaging, improvements in primary care management including ordering of diagnostic tests may involve consideration of appropriate imaging orders.

[252] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program.*

More specific to advanced diagnostic imaging, MIPS includes 10 specific quality measures pertaining to imaging or under the ''Diagnostic Radiology'' Specialty Measure Set. Additionally, the Meaningful Measures 2.0 Framework includes a priority area for safety with the goal of ''Reduced Preventable Harm'' (*https://edit.cms.gov/files/document/cascade-meaningful-measures-framework.xlsx*). An objective under this goal is ''Diagnostic Accuracy/Error'' which includes a cascade measure concept/family of ''Appropriate use of radiology and lab testing.'' An example of an existing measure within this concept is ''Appropriate Follow-up Imaging for Incidental Abdominal Lesions'' (*https://www.cms.gov/files/document/cascade-measures.xlsx*).

While a standalone program specifically requiring AUC consultation when ordering advanced diagnostic imaging services would directly target goals of improving advanced diagnostic imaging ordering patterns, our experience in recent years has demonstrated that the goals of appropriate, evidence based, coordinated care can be achieved more effectively, efficiently and comprehensively through other CMS quality initiatives.

7. Proposal To Rescind § 414.94

To execute this proposal and provide clarity to interested parties, we propose to amend our regulations to rescind the current regulations by removing the text of § 414.94 and reserve it for future use. This section contains the entirety of the regulations we adopted in the course of implementing elements of section 1834(q) of the Act. We believe the removal of these regulations is consistent with our proposal to pause efforts to implement the AUC program for reevaluation, and would avoid the potential confusion that could result if we were merely to retain or amend the regulation text at § 414.94.

We want to acknowledge and emphasize the value of clinical decision support to bolster efforts to improve the quality, safety, efficiency and effectiveness of health care. We welcome and encourage the continued voluntary use of AUC and/or clinical decision support tools in a style and manner that most effectively and efficiently fits the needs and workflow of the clinician user. Across many specialties and services, not just advanced diagnostic imaging, clinical decision support predates the enactment of the PAMA and, given its utility when accessed and used appropriately, we expect it to continue being used to streamline and enhance decision making in clinical practice and improve quality of care. Resources on clinical decision support are available on HHS Agency websites including the following:

- Office of the National Coordinator—*https://www.healthit.gov/topic/safety/clinical-decision-support.*
- Agency for Healthcare Research and Quality—*https://www.ahrq.gov/cpi/about/otherwebsites/clinical-decision-support/index.html.*
- Centers for Disease Control and Prevention—*https://www.cdc.gov/opioids/healthcare-admins/ehr/clinical-decision-support.html.*

8. Summary

In conclusion, we are proposing to pause efforts to implement the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94. We are not proposing a time frame within which implementation efforts may recommence. We will continue efforts to identify a workable implementation approach and will propose to adopt any such approach through subsequent rulemaking.

K. Medicare and Medicaid Provider and Supplier Enrollment

1. Medicare Enrollment

a. Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. The application is used for a variety of provider enrollment transactions, including the following:

- Initial enrollment—The provider or supplier is—(1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership—The provider or supplier is reporting a change in its ownership.
- Revalidation—The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515. (Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.)
- Reactivation—The provider or supplier is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540.
- Change of information—The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as we discuss in this section III.K. of this proposed rule, we

propose several changes to our existing Medicare provider enrollment regulations.

(We note that section III.K.2 of this proposed rule addresses a proposed change to one of our Medicaid provider enrollment provisions.)

b. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

c. Medicare Provider Enrollment Provisions

i. Revocation and Denial Reasons and Revisions to Other Revocation Policies

(A) Revocations

Under § 424.535(a), CMS may revoke a Medicare provider's or supplier's enrollment for any of the reasons specified within that paragraph. (The revocation grounds are currently identified as § 424.535(a)(1) through (22), with paragraphs (a)(15) and (16) designated as reserved.) These reasons include, for instance, the provider's or supplier's: (i) failure to adhere to Medicare enrollment requirements; (ii) exclusion by the HHS Office of Inspector General (OIG); (iii) felony conviction within the previous 10 years; (iv) pattern of improper or abusive billing, prescribing of Part B or Part D drugs, or ordering/referring/certifying of Medicare services or items; and (v) termination by another Federal health care program. A revocation is designed to safeguard the Medicare program, the Trust Funds, and beneficiaries by removing from (and preventing payment to) Medicare providers and suppliers that have engaged in problematic or otherwise non-compliant behavior. When a provider or supplier is revoked, they are generally barred from reenrolling in Medicare for a period of 1 to 10 years. The length of this ''reenrollment bar'' is determined based upon the severity of the basis of the revocation. The maximum reenrollment bar is typically restricted to egregious acts of misconduct.

We have previously finalized a number of regulations adding new revocation reasons to § 424.535(a) to address particular program integrity vulnerabilities and types of provider or supplier behavior. We have also used rulemaking to refine other policies regarding revocations, such as the reenrollment bar and the effective dates of certain revocations. Given our continuing obligation to assess potential vulnerabilities and establish payment safeguard measures, we believe that several additions and revisions to our revocation policies in § 424.535(a) are necessary at this time.

(1) Non-Compliance Revocation Ground (§ 424.535(a)(1))

Existing § 424.535(a)(1), in part, permits revocation if the provider or supplier is determined to not be in compliance with the enrollment requirements described in subpart P or in the enrollment application applicable to its provider or supplier type. We propose to change the language therein that reads ''described in this subpart P or in the enrollment application'' to ''described in this title 42, or in the enrollment application . . .'' This is because there are enrollment requirements located outside of 42 CFR part 424, subpart P; for instance, certain enrollment requirements pertaining to opioid treatment programs are in § 424.67(b). All enrollment requirements, regardless of their placement in title 42, must be adhered to, which is why we believe the scope of § 424.535(a)(1) should be expanded.

(2) Misdemeanor Convictions

As already alluded to, a provider or supplier can be revoked under § 424.535(a)(3)(i) if the provider, supplier, or any owner, managing employee, officer, or director of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. Section 424.535(a)(3)(ii) lists examples of such felonies, though they are not limited in scope and severity to these offenses.

Section 424.535(a)(3) does not include misdemeanor convictions, and there currently is no regulatory authority to revoke a provider or supplier based solely on a misdemeanor. However, we have become aware of and increasingly concerned about providers and suppliers convicted of misdemeanors for conduct that could endanger the Trust Funds' integrity and Medicare beneficiaries' health and safety. One case, for instance, involved a physician who wrote and filled prescriptions in fictitious patients' names to obtain Schedule II controlled substances for personal use. The physician pled guilty to a reduced misdemeanor charge for attempting to obtain controlled substances by fraud. In another situation, an owner of a provider was charged with felony assault with a dangerous weapon; the court reduced it to a misdemeanor as part of a guilty plea and sentenced the defendant to 2 years of probation.

We believe that our responsibility in overseeing the Medicare program requires that we have the ability to take protective action in such instances. To this end, we propose in new § 424.535(a)(16)(i) that CMS may revoke a provider's or supplier's enrollment if they, or any owner, managing employee or organization, officer, or director thereof, have been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. Proposed § 424.535(a)(16)(ii) would state that offenses under § 424.535(a)(16) include, but are not limited in scope or severity to, the following:

- Fraud or other criminal misconduct involving the provider's or supplier's participation in a Federal or State health care program or the delivery of services or items thereunder.
- Assault, battery, neglect, or abuse of a patient (including sexual offenses).
- Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct. (This example mirrors that in § 424.535(a)(3)(ii)(C) regarding felonies.)

Our proposal accounts for the fact that some States may classify a particular crime as a misdemeanor while others may deem it a felony; in other words, the misdemeanors included in proposed § 424.535(a)(16) may be treated as felonies in certain States. This reflects our concern about the seriousness of these actions. Indeed, merely because particular State statutes may designate the aforementioned actions as misdemeanors does not, in our view, lessen the risk the latter can pose to Medicare and its beneficiaries. It is, in short, the action itself, rather than its specific classification under State law, that is of principal concern to us.

We are soliciting comments on this proposal. We specifically are seeking feedback on: (1) whether there are any potential unintended consequences of our proposal that we are not considering; or (2) any guardrails we should consider so as not to create unintended consequences for persons with misdemeanor convictions.

(3) False Claims Act Civil Judgments

The False Claims Act (FCA) (31 U.S.C. 3729–3733) is the Federal government's principal civil remedy for addressing false or fraudulent claims for Federal funds. Section 3729(a)(1) of the FCA lists specific actions that can result in an FCA judgment against a defendant. These include the following:

- Knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.
- Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.
- Conspiring to violate any of the provisions in section 3729(a)(1) of the FCA.
- Having possession, custody, or control of property or money used, or to be used, by the government and knowingly delivering, or causing to be delivered, less than all of that money or property.
- Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the government and, intending to defraud the Government, making or delivering the receipt without completely knowing that the information on the receipt is true.
- Knowingly buying, or receiving as a pledge of an obligation or debt, public property from an officer or employee of the government, or a member of the Armed Forces, who lawfully may not sell or pledge property.
- Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government.

Under section 3729(a)(1), a party that is liable under the FCA must pay a civil penalty of between $5,000 and $10,000 for each false claim (though these amounts are periodically revised for inflation) and triple the amount of the government's damages.

Although the FCA's scope is not restricted to the health care arena and applies to all types of Federal government programs, the FCA has proven effective in helping to stem Medicare fraud. However, an FCA civil judgment against a provider or supplier does not, in and of itself, impact the latter's Medicare enrollment. Even if, for example, a provider is found to have knowingly submitted fraudulent claims and is liable for $100,000 in damages, we have no ability to revoke the provider's enrollment on this basis. This concerns us, for the actions identified in section 3729(a)(1) of the FCA involve serious misbehavior. We believe we must address this vulnerability to protect the Medicare program and its beneficiaries.

We accordingly propose in § 424.535(a)(15) that CMS could revoke the enrollment of a provider or supplier if the provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has had a civil judgment under the FCA imposed against them within the previous 10 years. (Strictly for purposes of (a)(15), however, the term ''civil judgment'' would not include FCA settlement agreements. The provision would require a judgment against the provider or supplier.) Recognizing that the specific facts and circumstances of each case will differ, we would consider the following factors in our decision:

- The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).
- The types of provider or supplier actions involved.
- The monetary amount of the judgment.
- When the judgment occurred.
- Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).
- Any other information that CMS deems relevant to its determination.

We note that we would include FCA civil judgments against owners, managing employees and organizations, and officers and directors (as those terms are defined in § 424.502) of the provider or supplier within the scope of this revocation basis. This is consistent with our approach to several other revocation reasons in § 424.535(a) and reflects our recognition that certain owning and managing parties exercise great influence over the provider or supplier organization and its daily operations. Should such a party have an FCA civil judgment against them, this could present a program integrity risk. We therefore believe that § 424.535(a)(15) should encompass such situations, though we would consider the degree of the owning or managing party's control over the provider or supplier (for example, percentage of ownership, scope of day-to-day operational authority) as a factor in our determination.

(4) Violation of Provider and Supplier Standards

Section 410.33(g) lists detailed enrollment standards that independent diagnostic testing facilities (IDTFs) must meet to enroll and maintain enrollment in Medicare. Likewise, § 424.57(c) identifies 30 enrollment standards that DMEPOS suppliers must meet as conditions of enrollment. These IDTF and DMEPOS standards address matters such as the maintenance of liability coverage, solicitation of patients, and customer service requirements. In addition, §§ 424.67(b) and (e), 424.68(c) and (e), and 424.205(b) and (d) contain enrollment standards and conditions for, respectively, opioid treatment programs (OTPs), home infusion therapy (HIT) suppliers, and Medicare diabetes prevention programs (MDPPs). The standards and conditions in §§ 410.33(g), 424.57(c), 424.67(b) and (e), 424.68(c) and (e), and 424.205(b) and (d) are in addition to, and not in lieu of, the more general enrollment requirements in 42 CFR part 424, subpart P with which IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, MDPPs, and all other provider and supplier types must comply.

We propose to add new paragraph (a)(23) to § 424.535 that would permit CMS to revoke an IDTF's, DMEPOS supplier's, OTP's, HIT supplier's, or MDPP's enrollment based on a violation of any standard or condition in, respectively, §§ 410.33(g), 424.57(c), 424.67(b) or (e), 424.68(c) or (e), or 424.205(b) or (d). No revocation reason in existing § 424.535(a) specifically references these regulatory paragraphs or violations thereof. Although we have sometimes applied a comparatively broad revocation basis in § 424.535(a)(1) to certain non-compliant IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, and MDPPs (for example, an invalid practice location under § 424.535(a)(5)), we believe a narrower approach that allows us to target violations of the aforementioned standards and conditions is preferable. That is, our proposal would more directly tie these regulatory paragraphs to § 424.535(a) by establishing a new revocation reason restricted to non-compliance with any of them.

(5) Scope of § 424.535(a)(17)

Under § 424.535(a)(17), we may revoke enrollment if the provider or supplier has an existing debt that CMS appropriately refers to the United States Department of Treasury. In determining whether a revocation is appropriate, CMS considers the six factors outlined in § 424.535(a)(17)(i) through (vi); these include, for instance, the reason for the provider's or supplier's failure to pay the debt. Section 424.535(a)(17)'s purpose is to spur providers and suppliers to repay their financial obligations to Medicare; in our view,

their failure to do so raises doubts as to whether the provider or supplier can be a reliable partner of the Medicare program.

We have received inquiries from interested parties concerning the scope of this provision, such as whether paragraph (a)(17) applies to debts that are no longer being collected or are being appealed. We propose to revise paragraph (a)(17) to address these issues.

First, and to help accommodate our revisions, existing § 424.535(a)(17)(i) through (vi) would be re-designated as paragraphs (a)(17)(i)(A) through (F).

Second, in new paragraph (a)(17)(ii), we propose to exclude from paragraph (a)(17)(i)'s purview those cases where: (1) the provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or (2) the administrative appeals process concerning the debt has not been exhausted or the timeline for filing such an appeal, at the appropriate appeal level, has not expired. In our view, the debts in these two situations have not been finally and fully adjudicated for purposes of paragraph (a)(17)(i)'s applicability. For this reason, we believe basic fairness to the provider or supplier justifies revised paragraph (a)(17)(ii).

Third, in § 424.535(a)(17)(i) we would change the term ''existing debt'' to ''failure to repay a debt''. This would allow us to potentially use our revocation authority even if collection action has ceased and the debt was ultimately terminated as a result, since the provider or supplier had still failed to repay it. Our central concern is more with the provider's or supplier's inaction in fulfilling its financial obligations to Medicare than with the particular status or result of CMS' collection efforts. In other words, and as with all of our revocation reasons in § 424.535(a), the issue is the provider's or supplier's conduct, which, in the case of § 424.535(a)(17), involves the provider's or supplier's failure to repay monies it owed to the Federal government. Simply because the debt could not be collected and was subsequently ''written off'' does not negate the fact that the provider or supplier did not meet its responsibility to repay it in the first place. Although the financial obligation may no longer constitute a debt because it was ''written off'', the core point is that it was a debt at one time but the provider did not repay it. Again, it is the provider's non-payment of the debt when it was current rather than whether said debt still exists that is critical, hence our proposed move away from ''existing debt'' to a status that better reflects the provider's inaction irrespective of the timing of the debt. In our view, a provider's failure to fulfill its financial obligations to the Medicare program: (1) constitutes a potential vulnerability to the program; and (2) could well increase the likelihood that any of the provider's or supplier's future Medicare debts, too, may not be repaid. Our obligation to safeguard the Trust Funds, we believe, requires us to have authority to take action to help prevent the latter occurrence. For these reasons, we believe our proposed change is warranted.

Nevertheless, we recognize that our proposed revision to § 424.535(a)(17)(i) might cause concern within the provider community, for there could be numerous reasons behind the ''writing off'' of a Medicare debt. For example, a provider may have been unable to repay a particular debt (that was later written off) because of a severe local emergency or natural disaster. While we would retain the authority to revoke under paragraph (a)(17)(i), we emphasize that we would still apply the aforementioned six factors in all potential revocation cases under paragraph (a)(17). Indeed, one of these factors is the ''reason(s) for the failure to fully repay the debt (to the extent this can be determined)'', and we will continue to carefully consider the factual circumstances behind the repayment failure so as to ensure fairness to the provider or supplier.

(B) Reasons for Denial

As already discussed, we are proposing new revocation authorities in § 424.535(a)(15), (16), and (23). We believe the rationales for these revocation reasons are equally applicable to newly enrolling providers and suppliers. Our program integrity concerns are the same regardless of whether the provider or supplier is already enrolled or is attempting to enroll; in either case, we must protect the Trust Funds and beneficiaries from problematic parties. Consequently, we propose to largely duplicate these new revocation reasons and establish concomitant grounds in § 424.530 for denying enrollment as follows.

First, § 424.530(a)(1), like § 424.535(a)(1), addresses the need for compliance with subpart P's enrollment requirements. We propose to change this reference from subpart P to title 42. As already noted, several sections of title 42 contain enrollment requirements outside of those in subpart P and to which the provider or supplier must adhere.

Second, we propose in new § 424.530(a)(16)(i) that CMS may deny a provider's or supplier's enrollment application if they, or any owner, managing employee or organization, officer, or director thereof, has been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. (Section 424.530(a)(16)(ii) would mirror proposed § 424.535(a)(16)(ii).) Our concern is that we currently have no legal authority to deny enrollment based on misdemeanor convictions for behavior that could endanger the Trust Funds or Medicare beneficiaries.

Third, new § 424.530(a)(17) would permit CMS to deny a provider's or supplier's enrollment application if the provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has had a civil judgment under the FCA imposed against them within the previous 10 years. The same factors for consideration in § 424.535(a)(15) would be included in § 424.530(a)(17). Given our previously stated view that the actions identified in section 3729(a)(1) of the FCA involve serious misbehavior, we believe proposed § 424.530(a)(17) would help protect the integrity of the Medicare program.

Fourth, and for the same reasons we are proposing new § 424.535(a)(23), we would duplicate the latter in new denial reason § 424.530(a)(18). We must strive to ensure that enrolling IDTFs, DMEPOS suppliers, OTPs, HIT suppliers, and MDPPs are legitimate providers and suppliers, as evidenced in part by their compliance with the standards and conditions applicable to them.

(C) Effective Date of Revocation

Section 424.535(g) addresses revocation effective dates. It states that a revocation becomes effective 30 days after CMS or the contractor mails notice of its determination to the provider or supplier. Yet there are exceptions. If the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or non-operational practice location, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation, or the date that CMS or its contractor determined that the provider or supplier was non-operational. The purpose of these exceptions is to prevent payment to a provider or supplier while it is out of compliance with Medicare enrollment requirements. To illustrate, assume a supplier's license is revoked on June 1. CMS learns of this and mails a revocation notice to the

supplier on June 15. If we applied the aforementioned ''30 days after mailing'' policy, the supplier could bill and be paid for services furnished between June 1 and July 15 while unlicensed. Per existing § 424.535(g), however, the revocation would be effective June 1, meaning all services furnished after that date would be ineligible for payment.

We view § 424.535(g)'s four exceptions as an important program integrity protection against improper payments. We do not believe providers and suppliers should be paid for services furnished during a period of non-compliance. With this principle in mind, we propose a number of policy and organizational changes to § 424.535(g).

First, we would split existing § 424.535(g) into several paragraphs. Paragraph (g)(1) would include the previously mentioned 30-day effective date policy, though with the following language at its beginning, ''Except as described in paragraphs (g)(2) and (g)(3) of this section''. New paragraph (g)(2) would list the four retroactive revocation situations in existing § 424.535(g). Each situation (and its associated revocation effective date) would be incorporated into a separate sub-paragraph to make paragraph (g)(2) clearer and more readable.

Second, paragraph (g)(2) would include the following additional situations where a retroactive effective date would be warranted:

- Revocations under proposed § 424.535(a)(16) (regarding misdemeanor convictions): the effective date would be the date of the misdemeanor conviction.
- Revocations based on a State license surrender in lieu of further disciplinary action: the effective date would be the date of the license surrender.
- Revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid): the effective date would be the date of the termination.
- Revocations based on termination of a provider agreement under 42 CFR part 489: the effective date would be, as applicable to the type of provider involved, the later of the following: (1) the date of the provider agreement termination; or (2) as applicable, the date that CMS establishes under 42 CFR 489.55. (Section 489.55 permits payments beyond the provider agreement termination date in certain instances and for a certain period.)
- Revocations based on proposed § 424.535(a)(23) would be as follows:

++ If the standard or condition violation involved the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the revocation effective date would be the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

++ If the standard or condition violation involved a non-operational practice location (for example, an IDTF's failure to maintain a physical facility on an appropriate site per § 410.33(g)(3)), the revocation effective date would be the date the non-operational status began.

++ If the standard violation involved a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the revocation effective date would be the date of the felony conviction.

(For all other standard violations, the effective date in paragraph (g)(1) would apply if the effective date in new paragraph (g)(3) (discussed later in this section of the proposed rule) does not.)

As with our existing four bases for a retroactive revocation, these new grounds would help ensure that providers and suppliers do not receive payment for services rendered while non-compliant with enrollment requirements. For example, a provider's State license surrender would mean that the provider is not appropriately licensed (and can thus be revoked under § 424.535(a)(1)) and, accordingly, should not be paid by Medicare for furnished services while unlicensed. Concerning terminations under another Federal health care program, some such programs are occasionally delayed in reporting their actions to CMS, during which period CMS continues making payments to the affected provider or supplier until CMS receives notice of the termination. Any Federal program termination is of concern to us, which is why we promulgated a revocation reason based on this action. We believe that any such termination that leads to a Medicare revocation should consequently be retroactive to the date of the program termination since the latter stemmed from conduct that, in our view, was serious enough to warrant the subsequent revocation. Likewise, there could be a brief administrative time lapse between when a provider agreement is terminated and a Medicare revocation is effectuated, meaning that a provider without a required provider agreement might still receive payments beyond the provider agreement termination date or the date that CMS establishes under § 489.55. The aforementioned retroactive effective dates involving § 424.535(a)(23), meanwhile, generally mirror those currently in § 424.535(g) (for example, felony conviction).

Third, new § 424.535(g)(3) would state that if the action that triggered the revocation occurred before the provider's or supplier's enrollment effective date, the revocation effective date would be the enrollment effective date that CMS assigned to the provider or supplier. To illustrate, suppose an adverse legal action occurred on February 1 and the provider was enrolled effective April 1. Although CMS was unaware of the action at the time of enrollment, it revoked the provider on April 15 upon learning of it. The revocation effective date would be April 1 rather than February 1. The aim of § 424.535(g)(3) is merely to reiterate that we could not apply a revocation effective date that is earlier than the date the provider or supplier is enrolled. It is a technical, though, we believe, obvious clarification.

(D) Timeframes for Reversing a Revocation Under § 424.535(e)

Section 424.535(e) states that if a revocation was due to adverse activity (sanction, exclusion, felony) by one of the parties listed in § 424.535(e) (for example, owner, managing employee, authorized or delegated official, supervising physician), the revocation can be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation notification. We have been concerned about this 30-day period. We do not believe a provider or supplier should be afforded so much time to terminate this business relationship; each day the revoked provider or supplier remains affiliated with the party in question, the more Medicare dollars that could be paid until the 30-day timeframe expires. It is the provider's or supplier's constant responsibility to ensure that its owning and managing personnel present no program integrity risks to the Medicare program. To give the provider or supplier 30 days to terminate a relationship that should have been promptly ended upon the commission of the adverse action (for example, when the owner became excluded) would be inconsistent with our obligation to protect the Trust Funds; it could also convey a false impression that maintaining affiliations with problematic parties is acceptable so long as the relationship ceases within a month of the revocation notice. To this end, we propose to revise § 424.535(e) to reduce the 30-day period therein to 15

days. We are not proposing, for instance, a 5-day period because we recognize that it might be administratively and financially difficult to immediately terminate the business relationship in question, especially an owner's interest in the provider or supplier. Still, the reduction from 30 days to 15 days evidences our concern about making Medicare payments to providers and suppliers that have relationships with parties presenting program integrity risks.

We emphasize that this change would have no impact on a revoked provider's or supplier's ability to appeal a revocation under 42 CFR part 498. It would only affect the provider's or supplier's utilization of § 424.535(e) to reverse the revocation. We are soliciting comments on whether 15 days is an appropriate timeframe.

ii. Stay of Enrollment

CMS may deactivate a provider's or supplier's Medicare billing privileges for any of the reasons specified in § 424.540(a). A deactivation differs from a revocation in that the former: (1) merely involves the stoppage, rather than the termination, of the provider's or supplier's billing privileges; and (2) does not entail any reenrollment bar under § 424.535(c). The latter is a particularly important distinction, for a deactivated provider or supplier can reactivate its billing privileges by following the procedures in § 424.540(b). It need not wait (as a revoked provider or supplier must) for the expiration of the 1 to 10-year bar period referenced in § 424.535(c) before attempting to restore its ability to bill Medicare. Indeed, we sometimes impose a deactivation instead of a revocation when we believe a more modest sanction is warranted.

Nevertheless, a deactivation can still impose a potential burden on a provider or supplier. This is especially true concerning § 424.540(e), which prohibits a provider or supplier from receiving payment for services or items furnished while deactivated. While deactivation is a less severe action than a revocation, it may be too punitive in certain cases. We believe that a middle ground between a deactivation and non-action on our part is warranted. In our view, we need as much flexibility as possible to take appropriate, fair, and reasonable measures that are commensurate with the degree of the provider's or supplier's action, inaction, or non-compliance.

For these reasons, we propose in new § 424.541 a new enrollment status labeled a ''stay of enrollment.'' This would be a preliminary, interim status—prior to any subsequent deactivation or revocation—that would represent, in a sense, a ''pause'' in enrollment, during which the provider or supplier would still remain enrolled in Medicare; in this vein, CMS would neither formally nor informally treat the stay as a sanction or adverse action for purposes of Medicare enrollment. We would also notify the affected provider or supplier in writing of the stay.

There would be two prerequisites for a stay's implementation. First, the provider or supplier must be non-compliant with at least one enrollment requirement in Title 42. Mere suspicion of or information alleging non-adherence is insufficient. Actual non-compliance is required. Second, CMS ascertains that the provider or supplier can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application (hereafter collectively referenced ''Form CMS–855 change request'' or ''change of information application''). This change request could involve, for instance, reporting a new street number (to illustrate, a provider's address changed from 10 Smith Street to 15 Smith Street) that the provider previously failed to disclose to CMS. We believe that using the aforementioned, comparatively bright-line Form CMS–855 submission standard would furnish clarity as to the types of non-compliance that can be remedied under our proposal and the specific vehicle for said remedial action.

When a ''stay period'' is imposed, the provider or supplier would not receive payment for services or items furnished during this period. These services and items would not be payable because the provider or supplier was non-compliant with enrollment requirements and thus not entitled to payment, even after the stay concludes. To permit payment for these services and items would be contrary to our obligation to safeguard the Trust Funds.

Although we acknowledge that this denial of payment is similar to what occurs with a deactivation under § 424.540, there are critical differences between the two actions. First, § 424.541 would make clear that a stay period lasts no more than 60 days. A deactivation, on the other hand, has no finite timeframe, meaning that services and items might not be payable for a long period of time if the provider or supplier does not submit the required reactivation application. Second, MACs can generally process Form CMS–855 change requests more rapidly than a reactivation application. A provider or supplier subject to a stay could therefore begin receiving payments sooner than would a deactivated provider or supplier. Third, while a reactivation application typically involves the provider's or supplier's completion of the entire Form CMS–855, a change of information application may only involve the submission of a limited amount of data (such as the information that is changing and basic identifying data). Completion of a change of information application is, in sum, considerably less burdensome for providers and suppliers than completion of a reactivation application.

Indeed, the issue of burden is the core consideration behind our proposal. As previously indicated, we do not wish to have to proceed to a deactivation (much less a revocation) in all cases of non-compliance. This is especially true if CMS believes in a particular case that the non-adherence can be fairly quickly corrected via the provider's or supplier's submission of updated enrollment data. Although we again recognize that payments for services and items furnished during the stay would not be covered, we emphasize that this would also be the case if CMS instead imposed a deactivation or revocation, with the important distinction that the period of non-payment would often be significantly shorter with a stay than with a deactivation and certainly a revocation. In all, we believe that our stay provision would ultimately reduce the burden on providers who would otherwise be deactivated or revoked for non-compliance.

Notwithstanding this, we believe the affected provider or supplier should have an opportunity to raise a concern about a stay by submitting a rebuttal. The rebuttal process would generally mirror that for deactivations and payment suspensions (outlined in 42 CFR 424.546 and 405.374, respectively), the two actions most akin to a stay. We recognize that given the comparatively and rather short time period that a stay would typically entail, many stays would have long expired by the time a provider or supplier files a rebuttal and CMS makes its determination thereon. In addition, if the provider or supplier can quickly return to compliance, they may likely pursue this course rather than submit a rebuttal (although the provider or supplier may still do so). Yet merely because some providers and suppliers might forego submitting a rebuttal does not mean the process should be unavailable to them.

Consistent with all of the foregoing, we propose a number of provisions in § 424.541. In paragraph (a)(1), we propose that CMS may stay an enrolled

provider's or supplier's enrollment if the provider or supplier:

- Is non-compliant with at least one enrollment requirement in Title 42; and
- Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application.

We emphasize that our authority to impose a stay would be discretionary. CMS would not be required to stay the provider's or supplier's enrollment. We could, for instance, elect to proceed directly to a deactivation or revocation (if grounds exist for either) without applying a stay as a prerequisite thereto. Our decision as to which action is most appropriate would depend upon the facts and circumstances of the case at issue.

In paragraphs (a)(2)(i) and (ii), respectively, we would state that during the period of any stay imposed under § 424.541:

- The provider or supplier remains enrolled in Medicare; and
- Claims submitted by the provider or supplier with dates of service within the stay period will be denied.

In paragraph (a)(3), we propose that a stay of enrollment would last no longer than 60 days from the postmark date of the notification letter. We believe a 60-day period would give the provider or supplier adequate time to submit the required Form CMS–855 change of information application.

In paragraph (a)(4), we propose that CMS must notify the affected provider or supplier in writing of the stay's imposition.

In paragraph (b), we would outline our proposed rebuttal process, which, as stated, would largely align with that for deactivations and payment suspensions.

In paragraph (b)(1), we propose that if a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under § 424.541, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay as described in § 424.541.

In paragraph (b)(2), we propose that CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1).

In paragraphs (b)(3)(i) through (iv), we propose that the rebuttal must:

- Be in writing.
- Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.
- Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.
- Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or non-physician practitioner), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in § 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

In paragraph (b)(4), we propose that the provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all of the requirements of paragraph (b)(3) of § 424.541 constitutes a waiver of all rebuttal rights under this section.

In paragraph (b)(5), we propose that upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

In paragraph (b)(6), we propose that a determination made under paragraph (b) is not an initial determination under § 498.3(b), and therefore, not appealable.

In paragraph (b)(7), we propose that nothing in paragraph (b) requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5).

We propose in paragraph (b)(8) to clarify the interaction between a stay and a subsequent deactivation or revocation.

In paragraph (b)(8)(i), we propose that nothing in paragraph (b) would require CMS to delay the imposition of a deactivation or revocation pending the completion of the review described in paragraph (b)(5) of this section. We believe we must retain the discretion to apply a subsequent deactivation or revocation should circumstances warrant.

In paragraph (b)(8)(ii)(A), we propose that if CMS deactivates the provider or supplier during the stay, any rebuttal to the stay the provider or supplier submits that meets the requirements of § 424.541 would be combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal. (This is meant to facilitate efficiency and simplicity in the review process of both rebuttals.) In paragraph (b)(8)(ii)(B), however, we propose that in all cases other than that described in paragraph (b)(8)(ii)(A), a stay rebuttal that was submitted in compliance with § 424.541 would be considered separately and independently of any review of any other rebuttal or, for revocations, appeal.

Finally, existing § 424.555(b) states that payment may not be made for Medicare services and items furnished to a Medicare beneficiary by a deactivated, denied, or revoked provider or supplier. The paragraph further states that the beneficiary has no financial liability for such services and items provided by these providers and suppliers. To clarify the issues of payment and beneficiary liability for purposes of § 424.541, we propose to add providers and suppliers currently under a stay of enrollment to the categories of providers and suppliers falling within the scope of § 424.555(b).

iii. Reporting Changes in Practice Location

Consistent with §§ 424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii), respectively, the following provider and supplier types must report a change in practice location within 30 days of the change: (1) DMEPOS suppliers; (2) IDTFs; and (3) physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations. All other provider and supplier types are required per § 424.516(e)(2) to report practice location changes within 90 days of the change. As explained below, we propose two sets of regulatory revisions regarding practice location changes. First, we propose to revise § 424.516(e)(1) to require therein such location changes involving providers and suppliers other than the categories previously described to be reported within 30 days of the change. Second, we would clarify in §§ 410.33(g)(2), 424.516(d)(1)(iii), and 424.516(e)(1) that a change of practice location includes adding a new location or deleting an existing one.

We have recently discovered instances where certain provider and supplier types not addressed in §§ 424.57(c)(2), 410.33(g)(2), or 424.516(d)(1)(iii), have moved their practice location without notifying CMS. This is problematic for two reasons. One is that Medicare payments are often based on the provider's or

supplier's specific geographic location. If we are not timely informed of the change in location, CMS could be making incorrect payments to the provider or supplier for an extended period (for instance, 90 days); this would be inconsistent with CMS's obligation to protect the Trust Funds. The other reason is that we would be unable to promptly determine whether the new site is compliant with Medicare provider enrollment requirements (for example, via a site visit) because we would not yet know of the change. The provider or supplier might be furnishing services from an invalid location, hence resulting in improper payments. CMS needs to ensure the accuracy of its payments, and being more rapidly advised of critical data like a practice location change would help facilitate this. It would also facilitate consistency with the aforementioned 30-day requirement in §§ 424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii).

For purposes of reporting practice location changes, we have traditionally included additions and deletions of locations within the scope of such changes. There is as much payment safeguard risk with belatedly reported additions and deletions as with changes. Paying a provider or supplier for services it furnishes at an unreported newly-established location could involve improper payments because, again, CMS does not even know whether the site meets all provider enrollment requirements; likewise, CMS could be paying a provider or supplier for services related to a location that was deleted and no longer exists. To make certain we are more promptly notified of practice location additions and deletions, we propose to revise §§ 410.33(g)(2), 424.516(d)(1)(iii), and 424.516(e)(1) to reiterate that these two transactions must be reported within 30 days of the addition or deletion. (A similar revision to § 424.57(c)(2) is unnecessary because all changes to enrollment data (including practice location additions, deletion, and changes) must already be reported within 30 days.)

iv. Definitions

We are also proposing several new and clarified definitions to help explain the meaning of certain provider enrollment concepts.

(A) ''Pattern or Practice''

Several of our existing Medicare enrollment revocation reasons are based upon the provider or supplier engaging in a pattern or practice of conduct. These reasons include all of the following:

- Section 424.535(a)(8)(ii): The provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.
- Section 424.535(a)(14): The physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements.
- Section 424.535(a)(21): The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

In determining whether such a pattern or practice exists and if a revocation under any of these authorities is warranted, CMS considers the factors specified in § 424.535(a)(8)(ii), (14), and (21), respectively.

We have received questions from interested parties over the years as to what constitutes a pattern or practice under these provisions. We have always made these determinations on a case-by-case basis, using the above-referenced factors. We do not propose to change this general procedure, for it gives us the flexibility we need to address each situation on its own facts and circumstances. Every case is different, and our factors are designed to account for this. Nonetheless, and to furnish elucidation to the provider community, we believe that certain minimum regulatory parameters are appropriate. This would be based on our past experience in applying § 424.535(a)(8)(ii), (14), and (21), our review of the factors therein, and the factual circumstances we have encountered in these cases.

To this end, we propose to establish a definition of ''pattern or practice'' in § 424.502. It would mean:

- For purposes of § 424.535(a)(8)(ii), at least three submitted non-compliant claims.
- For purposes of § 424.535(a)(14), at least three prescriptions of Part B or Part D drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.
- For purposes of § 424.535(a)(21), at least three orders, certifications, referrals, or prescriptions of Medicare Part A or B services, items, or drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

We recognize that our minimum threshold of three might appear small upon first impression. Yet interested parties should not assume that three non-compliant claims, orders, etc. would always trigger a revocation. To the contrary, it would often take more than three (and, on occasion, considerably more) to warrant revocation action. In only the rarest of circumstances would we revoke based on three claims, referrals, etc., and these would typically involve egregious non-compliance by the provider or supplier; we specifically chose three as our threshold to account for these isolated instances. We assure the provider community that, in every case, we would continue to diligently consider the factors outlined in § 424.535(a)(8)(ii), (14), and (21) and would treat the provider or supplier fairly given the facts presented. Our proposed definition in no way negates the validity or importance of these factors; its sole purpose is to furnish greater clarity to the provider community.

To accommodate our definition, we also propose to make several technical changes to § 424.535(a)(8)(ii), (14), and (21).

The introductory paragraph of § 424.535(a)(8)(ii) reads: ''CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:''. We are concerned that this language could be construed as meaning that so long as the ''pattern or practice'' definition in § 424.502 is met—that is, at least three non-compliant claims, orders, etc., were involved—a § 424.535(a)(8)(ii) revocation must automatically follow. As previously discussed, this is untrue. Even if the definition's threshold is met, we would then consider the entirely separate question of whether a revocation is warranted. In other words, the first step in our analysis would be to ascertain whether the activity involved qualifies as a ''pattern or practice.'' If (and only if) it does, the second step would be to determine, using the specified factors, whether the provider or supplier should be revoked. To clarify this approach, we propose to change § 424.535(a)(8)(ii)'s opening paragraph to state: ''CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements and that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS

considers, as appropriate or applicable, the following:''.

Language similar to that in existing § 424.535(a)(8)(ii) is present in § 424.535(a)(14)(i) and (ii). For the reasons outlined in the previous paragraph, we propose to revise the opening of § 424.535(a)(14)(i) to state: ''The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries, or both, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:''. The revised opening of § 424.535(a)(14)(ii) would read: ''The pattern or practice of prescribing fails to meet Medicare requirements and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:''.

With respect to § 424.535(a)(21), the closing language of the first sentence and the entirety of the second sentence reads: ''. . . or otherwise fails to meet Medicare requirements. In making its determination as to whether such a pattern or practice exists, CMS considers the following factors:''. We propose to change this to state: ''. . . or otherwise fails to meet Medicare requirements, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:''.

(B) Indirect Ownership

We propose to define ''indirect ownership interest'' in § 424.502. Some interested parties have expressed uncertainty about what indirect ownership is. An understanding of indirect ownership is important for providers and suppliers because they are required to report on their enrollment application all of their 5 percent or greater indirect owners. Section 420.201 defines an ''indirect ownership interest'' as ''any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.'' We believe this definition (albeit with certain modifications for purposes of clarity and to conform to the terminology of part 424, subpart P) would provide the desired elucidation. Accordingly, our proposed definition of ''indirect ownership interest'' would state:

- Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier. (For example, Provider A is owned by Entity B. Entity B is owned by Entity C. Entity C would have an indirect ownership interest in (and be an indirect owner of) Provider A.)
- Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier. (Using the preceding example, if Entity D had an ownership interest in Entity C, Entity D would have an indirect ownership interest in Provider A.)

We would designate this portion of our definition as paragraphs (1)(i) and (ii). To further clarify the concept of indirect ownership, we propose in paragraph (2) to mirror an example contained in § 420.202(a). Paragraph (2) would state: ''The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership entity in the provider or supplier and need not be reported.''

(C) PTs and OTs in Private Practice and Speech-Language Pathologists

Physical therapists in private practice (PTPPs), occupational therapists in private practice (OTPPs), and speech-language pathologists (SLPs) are permitted under the Act to receive payment for furnished Medicare services. However, they do not fall within the regulatory definition of ''supplier'' under § 400.202. The reason is that while the services they provide are payable under Medicare (thus allowing these individuals to enroll in the program), PTPPs, OTPPs, and SLPs are not formally recognized in either the Act or the CFR as types of ''suppliers.'' Nevertheless, we have applied the provisions of subpart P of part 424 to PTPPs, OTPPs, and SLPs via current guidance. We have also afforded PTPPs, OTPPs, and SLPs the same appeal rights (for example, appeals of enrollment denials and revocations) as all other enrolling or enrolled individuals and entities. To codify these practices in the CFR, we propose several regulatory provisions.

First, we propose to define ''supplier'' in § 424.502 as follows: ''Supplier means, for purposes of this subpart, all of the following: (1) the individuals and entities that qualify as suppliers under § 400.202; (2) physical therapists in private practice; (3) occupational therapists in private practice; and (4) speech-language pathologists.'' Second, we would include within new § 405.800(d) the same definition of ''supplier'' we are proposing in § 424.502. This is because subpart H of part 405 addresses various types of provider enrollment appeals under Medicare Part B. Third, 42 CFR part 498, too, contains various provisions concerning provider enrollment appeals. Section 498.2 defines ''supplier'' for purposes of part 498 by outlining several categories of suppliers. One such category, codified in paragraph (6) of this definition, reads, ''Physical therapist in independent practice.'' We propose to revise paragraph (6) to state: ''For purposes of this part, physical therapist in private practice, occupational therapist in private practice, or speech-language pathologist.''

(D) Authorized Officials

Under § 424.510(d)(3), an authorized official or delegated official must sign the Medicare enrollment application (for example, Form CMS–855A) on behalf of the provider or supplier if the latter is a corporation, partnership, group, limited liability company, or other organization. The terms authorized official and delegated official are defined in § 424.502. The former is ''an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.'' A delegated official is defined as an individual ''who is delegated by the 'Authorized Official' the authority to report changes and updates to the enrollment record. The delegated official must be an individual with ownership or control interest in, or be a W–2 managing employee of, the provider or supplier.''

With respect to the authorized official definition, interested parties have questioned CMS on whether the term ''organization'' as used therein means: (1) the entity listed in Section 2 of the Form CMS–855 as identified by its legal business name (LBN) and tax identification number (TIN); or (2) the provider or supplier type that is enrolling. To illustrate, suppose Entity A (with its unique LBN and TIN) submits three separate Form CMS–855A

initial enrollment applications to enroll an HHA, a hospice, and a skilled nursing facility (SNF), all of which have Entity A's LBN and TIN. In this type of situation, the question is whether ''organization'' refers to Entity A or instead to three separate ones—that is, the HHA, hospice, and the SNF.

We propose to add a sentence to the conclusion of the ''authorized official'' definition clarifying that the term ''organization'' therein—and exclusively for purposes of applying the ''authorized official'' definition—means the enrolling entity as identified by its LBN and TIN and not the provider or supplier type(s) that the entity is enrolling as. Using our previous illustration, this is because the HHA, hospice, and the SNF are not legal entities (such as corporations) separate and distinct from Entity A but are, in effect, part of Entity A itself; Entity A, in other words, is enrolling as an HHA, hospice, and SNF. In practical terms, this means an authorized official serves in that role on behalf of the enrolling entity (Entity A). Per our example, therefore, the individual could sign CMS provider enrollment applications concerning the HHA, hospice, and the SNF. We welcome comments on our proposed clarification.

2. Medicaid and CHIP Enrollment

a. Background

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program that (as of December 2022) covers more than 85 million low-income individuals. States have considerable flexibility when administering their Medicaid programs within a broad Federal framework, and programs vary from State to State. The Children's Health Insurance Program (CHIP) (title XXI of the Act) is a joint Federal and State health care program that (as of December 2022) provides health care coverage to over 7 million children in families with incomes too high to qualify for Medicaid, but too low to afford private coverage.

In operating Medicaid and CHIP, and as required by sections 1902(a)(78) and 2107(e)(1)(D) of the Act, respectively, each State requires providers to enroll if the providers wish to furnish, order, prescribe, refer, or certify eligibility for Medicaid or CHIP items or services in that State.[253] States may also establish their own provider enrollment requirements which must be met in addition to the applicable Federal provider enrollment requirements. Similar to Medicare provider enrollment, the purpose of the Medicaid and CHIP provider enrollment processes is to ensure that providers: (1) meet all Medicaid or CHIP requirements (and any other State-specific or Federal requirements); (2) are qualified to furnish, order, prescribe, refer, or certify Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

Different States may have different provider enrollment processes in operating their Medicaid and CHIP programs. However, all States must comply with Federal Medicaid and CHIP provider enrollment requirements, including those in part 455, subparts B and E.[254] For example, under subpart B, providers must disclose information regarding, among other things, ownership and control of the provider entity, certain business transactions, and criminal convictions related to Federal health care programs. Under subpart E, States must implement various Medicaid provider screening requirements. (In addition, State enrollment requirements must be consistent with section 1902(a)(23) of the Act and implementing regulations at § 431.51, under which States may set reasonable standards relating to the qualifications of providers; however, States may not restrict the right of beneficiaries to obtain services from any person or entity that is both qualified and willing to furnish such services.)

Another such provision in part 455 to which states must adhere involves denial or termination of enrollment. Under § 455.416, the State must deny or terminate a provider's Medicaid or CHIP enrollment for reasons specified therein, which include the following:

- Any person with a 5 percent or greater direct or indirect ownership interest in the provider fails to: (1) submit timely and accurate information; and (2) cooperate with any screening methods required under part 455, subpart E.
- Any person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with Medicare, Medicaid, or CHIP in the last 10 years.
- The provider, or a person with an ownership or control interest in or who is an agent or managing employee of the provider, fails to submit timely or accurate information as required.
- The provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the State Medicaid agency within 30 days of a CMS or a State Medicaid agency request.
- The provider fails to permit access to provider locations for any site visits under § 455.432.

Of particular importance, as will be discussed in more detail in this section III.K. of this proposed rule is that, under section 1902(a)(39) of the Act and § 455.416(c), the State must deny or terminate the provider's enrollment if the provider is terminated under the Medicare program, or the Medicaid program or CHIP of any other State.

These termination reasons require States to take action against providers that have, for instance, demonstrated an unwillingness or inability to meet certain Medicaid or CHIP requirements, or engaged in improper conduct. The possibility of being terminated also encourages providers to abide by Medicaid and CHIP enrollment rules, thus protecting Medicaid and CHIP against improper provider activity. Recognizing, however, that special circumstances may exist concerning a particular provider (and given the importance of leaving the States with as much discretion in their enrollment processes as possible), several of the otherwise mandatory termination reasons in § 455.416 permit the State to forgo termination if the State: (1) determines that such an action would not be in the Medicaid program's best interests; and (2) documents this decision in writing. Furthermore, States may develop additional State-specific reasons for terminating a Medicaid or CHIP provider, so long as such reasons (and the enforcement thereof) are not inconsistent with the requirements of §§ 455.416 and 431.51.

b. The 21st Century Cures Act's Medicaid and CHIP Provider Enrollment Requirements

The 21st Century Cures Act (Pub. L. 114–255; hereafter referred to as the Cures Act) was signed into law on December 13, 2016. The Cures Act addresses a variety of nationwide health care issues. Among the topics outlined in section 5005 of the Cures Act is Medicaid and CHIP provider enrollment and, in particular, Medicaid and CHIP provider terminations. For purposes of our proposals in this section III.K., the most pertinent provisions in section 5005 of the Cures Act are as follows:

- Section 5005(a)(1) of the Cures Act added a new paragraph (8) to section

[253] Section 1902(kk)(7) also requires physicians and other eligible professionals who order or refer Medicaid services and items to be enrolled in Medicaid. This requirement is made applicable to CHIP via section 2107(e)(1)(G) of the Act.

[254] All of subpart E, and 42 CFR 455.107 in Subpart B, are applicable to CHIP under § 457.990.

1902(kk) of the Act requiring the State to report the termination of a provider under Medicaid or CHIP to the Secretary within 30 days after the effective date of the termination. Section 5005(a)(1) of the Cures Act also outlines information that must be included in the termination notification that the State sends to CMS. However, paragraph (8)(A) limits this reporting requirement to terminations for reasons specified in § 455.101 as in effect on November 1, 2015, which are limited to terminations ''for cause'' (including, but not limited to, terminations for reasons relating to fraud, integrity, or quality). Paragraph (8)(B) provides that, for purposes of the reporting requirement, the effective date of a termination is the later of: (1) the effective date specified in the notice of termination; or (2) the date on which applicable appeal rights have been exhausted or the timeline for appeal has expired.

- Section 5005(a)(3) of the Cures Act added a new paragraph (ll) to section 1902 of the Act stating that within 30 days of receiving notification of a Medicaid or CHIP provider termination, the Secretary shall review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed under section 6401(b)(2) of the Affordable Care Act.
- Section 5005(a)(4)(A) of the Cures Act added a new paragraph (D) to section 1903(i)(2) of the Act providing that, except for emergency items or services (but not including items or services furnished in a hospital emergency department), no Federal financial participation (FFP) funds may be paid for items and services furnished by a provider terminated under Medicaid or CHIP (as described in section 1902(kk)(8)) beginning 60 days after the date the termination is included in the termination database.

We have issued extensive sub-regulatory guidance to assist States in implementing Medicaid and CHIP screening and enrollment provisions outlined in 42 CFR part 455. This guidance is compiled in a document titled ''Medicaid Provider Enrollment Compendium'' (MPEC) (*https://www.medicaid.gov/sites/default/files/2021-05/mpec-3222021.pdf*), originally issued in May 2016 and subsequently updated several times. After the enactment of the Cures Act, CMS again updated the MPEC to clarify the operational details concerning several of the statutory provisions amended by section 5005.

Under CMS' existing process (under the statute and MPEC guidance), when a State reports a ''for cause'' termination, CMS determines whether: (1) the State submitted the required termination data in accordance with section 1902(kk)(8) of the Act; and (2) the termination is, indeed, ''for cause.'' If CMS concludes that the reported termination is ''for cause'' and is thus appropriate to be included in the database referenced in section 1902(ll) of the Act, the information is uploaded into a CMS-managed database. This database contains information on Medicaid and CHIP terminations and Medicare revocations, the latter of which is updated at least monthly. The database enables a State to review Medicaid and CHIP terminations in other States, as well as Medicare revocations, and, under § 455.416(c), to deny enrollment or take its own termination action against a provider if the latter is also enrolled in the State. Moreover, the database gives CMS access to information on Medicaid and CHIP provider terminations nationwide, which permits us to take a Medicare revocation action against the provider under § 424.535(a)(12)(i), if appropriate, based on the Medicaid or CHIP termination.

c. Proposed Provisions

i. Termination Lengths—Background

There are two termination database-related matters that have generated uncertainty during our implementation of the § 455.416(c) termination requirement. They involve: (1) the length of time for which a termination remains active in the termination database; and (2) the interaction of different termination periods imposed by the States and/or the Medicare program.

Under § 424.535(c), if a Medicare provider or supplier is revoked from Medicare, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the reenrollment bar, which, under existing § 424.535(c), is generally for a period of 1 to 10 years. This 1- to 10-year period typically constitutes: (1) the time period for which the provider or supplier is revoked from Medicare; and (2) the amount of time that the Medicare revocation will remain in the termination database.

Many States have similar reenrollment bars for terminated Medicaid and CHIP providers. (Hereafter, and for purposes of consistency, the terms ''termination period'' and ''reenrollment bar'' as used in this section III.K. refer to a Medicaid or CHIP reenrollment bar, unless otherwise noted.) Yet these termination periods often differ among the States. For instance, State A may terminate a provider for 3 years for a particular transgression while State B might do so for 10 years for the same conduct. We recognize the traditional deference given to States regarding the establishment of reenrollment bars. However, the interplay between varying termination period lengths (especially as they relate to the termination database and the previously-mentioned termination requirement in § 455.416(c)) has caused confusion among the States, provider communities, and other interested parties. Accordingly, we propose to specify in regulation the length of time for which for cause provider terminations will remain in the database and, by extension, the period for which other States must deny or terminate the provider under to § 455.416(c).

ii. Revision to § 455.416(c)

As previously indicated, under § 455.416(c) the State Medicaid agency must deny or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act, or under the Medicaid program or CHIP of any other State. We propose to add the following clause to the end of § 455.416(c): ''and is currently included in the termination database under § 455.417.'' This revision would clarify that the denial and termination requirement under § 455.416(c) is predicated on the provider's inclusion in the termination database.

iii. Length of Inclusion in Database (§ 455.417)

For the reasons outlined above, we propose several provisions in new § 455.417 as follows:

- In paragraph (a)(1), we propose that a provider would remain in the termination database referenced in section 1902(ll) of the Act for a period that is the lesser of:

++ The length of the termination period imposed by the initially terminating State Medicaid program or CHIP, or the reenrollment bar imposed by the Medicare program; or

++ 10 years (for those Medicaid or CHIP terminations that are greater than 10 years).

- Under proposed paragraph (a)(2) all other State Medicaid programs or CHIPs in which the provider is enrolled or seeking to enroll would be required to terminate or deny the provider's enrollment from their respective programs (under § 455.416(c)) for at least the same length of time as the termination database period).

• In paragraphs (b)(1)(i) and (ii), respectively, we propose that nothing in paragraph (a) would prohibit:

++ The initially terminating State from imposing a termination period of greater than 10 years consistent with that State's laws, or

++ Another State from terminating the provider, based on the original State's termination, for a period: (A) of greater than 10 years; or (B) that is otherwise longer than that imposed by the initially terminating State.

In paragraph (b)(2), however, we would make clear that the period established under paragraph (b)(1)(ii) must be no shorter than the period in which the provider is to be included in the termination database under paragraph (a).

To illustrate how paragraphs (a) through (b) would work in practice, consider the following examples:

++ Example 1: State A, the initially terminating State, terminates a provider for a period of 5 years. Under paragraph (a)(1), the provider would remain in the termination database for 5 years. Under paragraph (b), when State B terminates the provider based on the State A termination (under § 455.416(c)), it may impose any termination period so long as (under proposed paragraph (b)(2)) it is no shorter than the 5-year period in which the provider remains in the termination database. (This is because all States must adhere, at a minimum, to the termination database period.) However, whatever period State B imposes would have no effect on the length of time the provider is to remain in the termination database, which is 5 years under the original State's (State A's) termination period. If, therefore, State B imposes an 8-year termination period, the provider would still only remain in the termination database for 5 years, but State B could (under its State law) prohibit the provider from enrolling in its State B Medicaid program or CHIP for another 3 years beyond that period.

++ Example 2: State A, the initially terminating State, terminates a provider for 15 years. Under paragraph (a)(1), the provider would remain in the termination database for only 10 years. Under paragraph (b), however, State A may enforce its original 15-year termination period imposed on the provider notwithstanding that the provider would only remain in the database for 10 years. When State B terminates the provider based on the State A termination (under § 455.416(c)), it may impose any termination period permitted under its State law so long as it is at least the length of the 10-year termination database period in this Example 2.

As indicated in Examples 1 and 2, there is a critical distinction between a State-imposed termination period (or a Medicare reenrollment bar) and the length of time in which a provider remains in the termination database. The former generally involves the period for which the provider is prohibited from reenrolling in the initially terminating State program or Medicare (in the case of a revocation); the latter involves the minimum period in which other States must also terminate the provider under § 455.416(c). (Hereafter, the former will be referred to as the ''termination period'' or ''reenrollment bar'' and the latter the ''termination database period.'')

Aside from the aforementioned need for clarity, there are several other important reasons for proposed § 455.417(a) and (b).

First, despite our aforementioned concerns about inconsistencies in State-imposed termination periods, we are committed to ensuring that States have as much discretion as possible in administering their respective Medicaid programs. We believe proposed § 455.417(a) and (b), taken together, would clarify the duration of the requirement to terminate under § 455.416(c) while preserving each State's ability to impose whatever termination period it deems appropriate (subject to proposed paragraph (b)(2), which designates the termination database period as a minimum).

Second, establishment of a maximum 10-year termination database period would address situations where a State imposes an extremely lengthy, or even a lifetime, termination period that is far longer than: (1) that imposed by other States for the same conduct; or (2) the maximum Medicare 10-year reenrollment bar under § 424.535(c), but other States wish to permit a provider to reenroll before the initially terminating State's reenrollment bar has expired. Moreover, a finite termination database period is needed to address instances where the initially terminating State establishes an indefinite termination period; if the termination remained in the database until that State permitted the provider to reenroll, this would essentially cause the provider to be barred from the Medicaid program in all States indefinitely, regardless of the underlying cause of the termination and the circumstances associated therewith. This could be very problematic for the provider and perhaps lead to access to care issues in some States. Indeed, providers may experience undue burden in these cases because even if they can prove that the underlying cause for the termination has been resolved, they might remain unable to enroll in other States while an indefinite termination remains in the termination database. We believe that a maximum 10-year period in the database (if the State imposes a termination period of 10 years or longer) would give the broadest possible deference to the initially terminating State while still providing a consistent and finite period during which other States are required to terminate (and continue the termination) or deny the provider's enrollment under § 455.416(c).

In paragraph (c)(1), we propose that if the initially terminating State agency or the Medicare program reinstates the provider prior to the end of the termination period originally imposed by the initially terminating State program or Medicare, CMS would remove the provider from the termination database after the reinstatement has been reported to CMS. This proposal is intended to clarify the impact of a reinstatement, including those occurring prior to the expiration of the original termination period. Such instances of early reinstatement might include: (1) resolution of the underlying basis for the original termination; or (2) access to care concerns of the originally terminating State agency. However, we also propose in § 455.417(c)(2) that if the provider is removed from the database due to reinstatement by the originally terminating State agency, nothing prohibits CMS from immediately re-including the provider in the database if a separate basis for doing so exists under 42 CFR part 455 or 424. This is to emphasize that CMS is not required to afford the provider any sort of ''waiting period'' between the expiration of the original termination period and the commencement of a new one should grounds exist for the imposition of the latter; the new termination database period can become effective immediately upon the expiration of the prior one.

Consider the following example of proposed § 455.417(c)(2)'s potential applicability. State A initially terminates a provider for 2 years. Under proposed § 455.417(a), the provider would be included in the termination database for 2 years. Under proposed § 455.417(b), all other States must terminate the provider from their Medicaid programs for at least that same time period. Yet Medicare is not required to (and elects not to) revoke the provider's Medicare enrollment notwithstanding the State A

termination. Now assume that State A reinstates the provider after 1 year. Two days before the reinstatement takes effect, though, the provider is revoked from Medicare with a 3-year enrollment bar for a reason unrelated to the grounds behind the State A termination. Since § 455.416(c) requires State A (and all other States) to terminate the provider based on the Medicare revocation, CMS may place the provider in the termination database for a 3-year period effective immediately upon the expiration of the original termination database period. This is to ensure that the initial 1-year period runs its full course before the beginning of the 3-year termination database. If we commenced the 3-year period 2 days before the 1-year period expired, the 1-year period would, in effect, have lasted 2 days less than 1 year; likewise, the 3-year period would essentially be 3 years minus 2 days. This is due to the 2-day overlap between the two timeframes.

Aside from clarifying that Medicaid termination periods can run consecutively without any break between them, we believe that proposed § 455.417(c) would help ensure a seamless transition between the two periods and, in the process, prevent problematic Medicaid providers from using any gap in periods to bill Medicaid.

We indicated earlier that, per the statute and MPEC guidance, States must report ''for cause'' terminations to CMS for purposes of the termination database. We propose in new § 455.417(d) that, for purposes of § 455.417 only, terminations under § 455.416(c) (which, as previously discussed, are based on another State's termination of the provider) are not themselves considered ''for cause'' terminations, and therefore, need not be separately reported to CMS for inclusion in the termination database. Using Examples 1 and 2 as previously discussed, this would mean that State B would not have to report the terminations in those examples to CMS for termination database purposes, although State B would still be required to: (i) terminate the provider under § 455.416(c), based on the State A termination; and (ii) apply a termination period no shorter than the termination database period established under § 455.417(a). The goal of proposed § 455.417(d) is to eliminate repetitiveness in reporting the same data to CMS so as to ease the burden on States. In our view, and under the foregoing example, there is no reason for State B (and, for that matter, other States) to expend resources in reporting a termination that was already reported by the originally terminating State. Furthermore, this would avoid the potential for additional confusion regarding the termination database period, in that it would ensure that such period is based only on the initial State's termination and not on subsequent derivative terminations.

L. Expand Diabetes Screening and Diabetes Definitions

For CY 2024, we propose to: (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test; (2) expand and simplify the frequency limitations for diabetes screening; and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening (§ 410.18(a)), Medical Nutrition Therapy (MNT) (§ 410.130) and Diabetes Outpatient Self-Management Training Services (DSMT) (§ 410.140).

Medicare coverage for diabetes screening tests under Part B are described in statute (sections 1861(s)(2)(Y), 1861(ww)(2)(K), 1861(yy), and 1862(a)(1)(M) of the Act) and in regulation at 42 CFR 410.18. The statute and regulations allow for diabetes screening tests:

- The Fasting Plasma Glucose (FPG) test (section 1861(yy)(1)(A) of the Act and § 410.18(c)(1));
- The Post Glucose Challenge Test, also called the Glucose Tolerance Test (GTT) (§ 410.18(c)(2)); and
- Such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations (section 1861(yy)(1)(B) of the Act) and that may be determined through a national coverage determination (§ 410.18(c)(3)).[255]

We propose to exercise our authority in section 1861(yy)(1) of the Act to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c), in consultation with recommendations by appropriate organizations.

Section 1861(yy)(3) of the Act limits the frequency of diabetes screening tests to not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. Our regulations allow two screening tests per calendar year if the patient was previously diagnosed with pre-diabetes and one screening test per year for patients who were previously tested who were not diagnosed with pre-diabetes, or who were never tested before (§ 410.18(d)). We propose to exercise our authority in section 1861(yy)(1)(3) of the Act to simplify our frequency limitations for diabetes screening by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

We also propose to simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a) to remove the codified clinical test requirements from the definition of ''diabetes.'' We also propose to remove the definition of ''pre-diabetes'' at § 410.18(a). The diabetes and prediabetes definitions at § 410.18(a) supported existing regulatory frequency limitations in § 410.18(d), which describe separate frequency limitations between individuals previously diagnosed, and those terms would no longer be needed under our proposed updates. We recognize that it is unnecessary to codify clinically specific test criteria into the regulatory definition of diabetes, which reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. The proposed revised definition of diabetes for screening purposes would be shortened to describe diabetes as diabetes mellitus, a condition of abnormal glucose metabolism.

Medicare coverage for MNT under Part B is described in statute (primarily sections 1861(s)(2)(V), 1861(vv), and 1861(ww)(2)(I) of the Act, in regulations at 42 CFR part 410, subpart G, and in National Coverage Determination (NCD) (Section 180.1 of the Medicare National Coverage Determinations Manual (NCD Manual)). Section 410.130 currently describes a number of definitions for purposes of the MNT benefit, including ''diabetes.'' The regulatory definition of diabetes for MNT purposes at § 410.130 is identical to the existing regulatory definition of diabetes for screening purposes at § 410.18(a). We propose to simplify the regulatory definitions of ''diabetes'' for the purpose of MNT at § 410.130 to remove the codified clinical test requirements. The proposed revised definition of diabetes for MNT purposes would be shortened to simply describe diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. NCD 180.1 refers to the regulatory definition of diabetes at § 410.130, so no modifications would be required to the NCD.

Medicare coverage for DSMT under Part B is described in statute (sections

[255] The Secretary, as of the date of this proposed rule, has not approved additional diabetes screening tests by through a national coverage determination.

1861(s)(2)(S), 1861(qq), 1861(ww)(2)(F) of the Act) and in regulation at part 410 subpart H. Section 410.140 describes a number of definitions for the purposes of the DSMT benefit, including ''diabetes''. The regulatory definition of diabetes for DSMT purposes at § 410.140 is identical to the existing regulatory definition of diabetes for MNT purposes at § 410.130 and the existing regulatory definition of diabetes for screening purposes at § 410.18(a). We propose to exercise our authority to simplify the regulatory definitions of ''diabetes'' for the purpose of DSMT at § 410.140 to remove the codified clinical test requirements. The proposed revised definition of diabetes for DSMT purposes would be shortened to simply define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism.

1. Background

Diabetes is a chronic disease that affects how the body turns food into energy and includes three main types: Type 1, Type 2 and gestational diabetes. The Centers for Disease Control and Prevention (CDC) reports that approximately 37.3 million Americans are living with diabetes and an additional 96 million Americans are living with prediabetes.[256] CDC reports that 326,000 persons age 65 years and older are newly diagnosed with diabetes each year. CDC also estimates that among persons age 65 years and older, 21 percent have been diagnosed with diabetes while 5 percent have undiagnosed diabetes.[257] Diabetes is the leading cause of kidney failure and new cases of blindness among adults, and the sixth leading cause of death among adults age 65 years and older in the U.S.[258] Screening is performed on persons who may not exhibit symptoms to identify persons with either prediabetes or diabetes, who can then be referred for appropriate prevention or treatment, with the intention of improving health outcomes.

In October 2015, the United States Preventive Services Task Force (USPSTF) issued a revised final recommendation statement, with a grade of B, for screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese and again identified the FPG, GTT and HbA1c tests as appropriate for diabetes screening.[259] In August 2021, the USPSTF issued a revised final recommendation statement, with a grade of B, that expanded recommended screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity, and that clinicians should offer or refer patients with prediabetes to effective preventive interventions, which are discussed in their report. The USPSTF again recommended the FPG, GTT and HbA1c tests as appropriate for diabetes screening and noted, ''Because HbA1c measurements do not require fasting, they are more convenient than using a fasting plasma glucose level (FPG) or an oral glucose tolerance test (GTT).'' [260] The grade of B is indicated when the USPSTF has high certainty that the net benefit is moderate or moderate certainty that the net benefit is moderate to substantial.

We recognize that both the USPSTF and specialty societies have identified the HbA1c test as clinically appropriate for diabetes screening. In addition, the HbA1c test has certain unique advantages and disadvantages compared to the FPG and GTT tests that should be considered by the practitioner and patient when choosing a diabetes screening test. The American Diabetes Association (ADA) Standards of Care in Diabetes—2023 reads, ''Generally, FPG, 2-h PG during 75-g OGTT (aka GTT), and A1C (aka HbA1c) are equally appropriate for diagnostic screening . . . The same tests may be used to screen for and diagnose diabetes and to detect individuals with prediabetes . . . A1C (aka HbA1c) has several advantages compared with FPG and OGTT (aka GTT), including greater convenience (fasting not required), greater preanalytical stability, and fewer day-to-day perturbations during stress, changes in nutrition, or illness. However, these advantages may be offset by the lower sensitivity of A1C (aka HbA1c) at the designated cut point, greater cost, limited availability of A1C (aka HbA1c) testing in certain regions of the developing world, and the imperfect correlation between A1C (aka HbA1c) and average glucose in certain individuals . . . Despite these limitations with A1C (aka HbA1c), in 2009, the International Expert Committee added A1C (aka HbA1c) to the diagnostic criteria with the goal of increased screening.'' [261] The American Association of Clinical Endocrinology (AACE) also recommends screening for diabetes and prediabetes with similar tests, including HbA1c.[262]

The regulatory texts for diabetes screening, MNT, and DSMT include a clinically specific test-based definition for ''diabetes'' that has since been overtaken by evolving clinical standards. Since 2020, the ADA has revised and expanded its criteria for the diagnosis of diabetes to also include the HbA1c test and a random plasma glucose test for a patient appearing to have hyperglycemia or hyperglycemic crisis.[263]

2. Statutory Authority

Section 613 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1861(yy) to the Act and mandated coverage of diabetes screening tests in the Medicare Part B program. Section 1861(yy)(1) of the Act describes diabetes screening tests as testing furnished to an individual at risk for diabetes for the purpose of early detection of diabetes, including the FPG test and such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(yy)(2) of the Act describes ''individual at risk for diabetes'' as an individual who has any of a number of listed risk factors, including obesity, defined as a body mass index greater than or equal to 30 kg/m^2 as an independent qualifying factor and overweight, defined as a body mass index greater than 25 kg/m^2, but less than 30, kg/m^2 (when present with a second qualifying factor including a family history of diabetes, a history of gestational diabetes and an age of 65 years or older. Section 1861(yy)(3) of the Act mandates that the Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be

[256] CDC website on diabetes at *https://www.cdc.gov/diabetes/basics/index.html*.

[257] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Accessed March 9, 2023. *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf*.

[258] Heron M. Deaths: Leading causes for 2019. National Vital Statistics Reports; vol 70 no 9. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: *https://dx.doi.org/10.15620/cdc:107021*.

[259] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-abnormal-blood-glucose-and-type-2-diabetes-october-2015*.

[260] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes*.

[261] Diabetes Care 2023;46(Suppl. 1):S19–S40: *https://doi.org/10.2337/dc23-S002*.

[262] Lawrence Blonde, Guillermo E. Umpierrez, S. Sethu Reddy, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan—2022 Update. Endocrine Practice, 2023; 28: 923–1049, *https://doi.org/10.1016/j.eprac.2022.08.002*.

[263] Diabetes Care 2020;43(Supplement_1):S14–S31, *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes*.

more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. Section 1861(yy) of the Act does not include a definition of diabetes.

Section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) added section 1861(vv) to the Act and mandated coverage of MNT under Part B. Section 1861(s)(2)(V) of the Act limits coverage of MNT to patients with diabetes or a renal disease. Section 1861(vv)(1) of the Act describes MNT, in pertinent part, as nutritional diagnostic, therapy, and counseling services for the purpose of disease management. Sections 1861(s)(2)(V) and (vv) of the Act do not include a codified definition of diabetes.

Section 4105(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) added section 1861(qq) to the Act and mandated coverage of DSMT. Section 1861(qq) of the Act describes DSMT, in part, as educational and training services furnished to an individual with diabetes by a certified provider in an outpatient setting by an individual or entity, but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge to participate in the management of the individual's condition. Section 1861(qq) of the Act does not establish a definition of diabetes.

3. Regulatory Authority and National Coverage Determinations

Our implementing regulations for diabetes screening tests are codified at § 410.18. The regulatory definition of diabetes and prediabetes for the purposes of diabetes screening were created, in part, to distinguish separate frequency limitations for each. Section 410.18(d) allows two diabetes screening tests per calendar year for individuals diagnosed with pre-diabetes and one diabetes screening test per calendar year for individuals previously tested who were not diagnosed with pre-diabetes, or who were never tested before. Section 410.18(e) limit diabetes screening to ''individual at risk for diabetes'' with a list of qualifying eligibility factors, including obesity, defined as a body mass index greater than or equal to 30 kg/m^2 as an independent qualifying factor (§ 410.18(e)(3)) and overweight, defined as a body mass index greater than 25 kg/m^2, but less than 30, kg/m^2 (when present with a second qualifying factor including a family history of diabetes, a history of gestational diabetes and an age of 65 years or older) (§ 410.18(e)(5)).

Our implementing regulations for MNT are codified at part 410 subpart G. Section 410.130 described a number of definitions for purposes of the MNT benefit, including ''diabetes.'' MNT is also described as a covered service at section 180.1 of the NCD Manual. NCD 180.1 does not include a codified definition of diabetes but does refer to ''diabetes, as defined at § 410.130.'' Our implementing regulations for DSMT are codified at part 410 subpart H. Section 410.140 describes a number of definitions for the purposes of the DSMT benefit, including ''diabetes.''

NCD 190.20, Blood Glucose Testing, describes the indications and limitations of blood glucose testing generally but refers to § 410.18 and the Claims Processing Manual for specific policies on diabetes screening. NCD 190.21, Glycated Hemoglobin/Glycated Protein, authorizes coverage of the HbA1c test for the management of diabetes but does not address screening for diabetes.

In the CY 2004 PFS final rule (68 FR 63195), we finalized proposals to adopt regulatory definitions of diabetes for the purposes of MNT and DSMT. We codified in regulatory text at §§ 410.130 and 410.140 that diabetes is defined as ''diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.'' The definition of diabetes was based, in part on a clinical recommendation submitted by the American Association of Clinical Endocrinologists. In the CY 2005 PFS final rule (69 FR 66235), we finalized proposals to adopt implementing regulations for diabetes screening, which was recently added as a Medicare covered benefit in the Section 613 of the MMA. We adopted a new regulatory definition of prediabetes as condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL, as well as including the conditions of impaired fasting glucose and impaired glucose tolerance. We also adopted the regulatory definition of diabetes finalized in the CY 2004 PFS for MNT and DSMT. Neither the statutes nor the regulatory text for diabetes screening, MNT and DSMT distinguish between different types of diabetes.

4. Proposed Revisions

We propose to exercise our authority in section 1861(yy)(1)(B) of the Act to add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c), consistent with a recently revised recommendation by the USPSTF. As described earlier in our proposal, the USPSTF recommended the HbA1C test for diabetes screening in their October 2015 and August 2021 revised final recommendation statements. We have engaged in meetings with appropriate organizations while developing our proposal to expand diabetes screening coverage, including the ADA, the Association of Diabetes Care & Education Specialists (ADCES), the National Clinical Care Commission (NCCC) and the Diabetes Advocacy Alliance (DAA). In addition, we consulted the published clinical recommendations from the USPSTF (described earlier), the ADA [264] and the AACE [265] in developing our proposal. We look forward to further consultation with organizations through the public notice and comment rulemaking process and invite public comment on our proposal.

We propose to exercise our authority in section 1861(yy)(1)(3) of the Act to expand and simplify our frequency limitations for diabetes screening by aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual. We also propose to remove the regulatory definition of pre-diabetes for the purposes of diabetes screening at § 410.18(a), which functionally served, in part, to distinguish the separate frequency limitations of diabetes screening at two diabetes screening tests per calendar year for individuals diagnosed with pre-diabetes and one diabetes screening test per calendar year for individuals previously tested who were not diagnosed with pre-diabetes, or who were never tested before (§ 410.18(d)). Our proposal to remove the regulatory definition of pre-diabetes is intended to simplify and expand diabetes screening while reducing unnecessary regulatory complexity. We recognize that pre-diabetes and diabetes exist on a continuum and both are screened and identified through common diabetes screening tests. Our proposal to remove

[264] *https://diabetesjournals.org/care/article/45/Supplement_1/S17/138925/2-Classification-and-Diagnosis-of-Diabetes.*

[265] *https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.*

the regulatory definition of pre-diabetes does not reflect a change in our position on pre-diabetes screening and treatment as a Medicare benefit. In making this proposal we recognize that the FPG, GTT and HbA1c tests include different levels of burden for the patient and also measure different aspects of diabetes pathology. The August 2021 USPSTF revised final recommendation statement states ''HbA1c is a measure of long-term blood glucose concentration and is not affected by acute changes in glucose levels caused by stress or illness. Because HbA1c measurements do not require fasting, they are more convenient than using a fasting plasma glucose level or an oral glucose tolerance test. Both fasting plasma glucose and HbA1c levels are simpler to measure than performing an oral glucose tolerance test. The oral glucose tolerance test is done in the morning in a fasting state; blood glucose concentration is measured 2 hours after ingestion of a 75-g oral glucose load. The diagnosis of prediabetes or type 2 diabetes should be confirmed with repeat testing before starting interventions.'' [266] We have engaged in meetings with appropriate organizations while developing our proposal to expand diabetes screening coverage, including the ADA, the ADCES, the NCCC, and the DAA. We also consulted with the written recommendations of a number of specialty societies and the USPSTF in developing our proposal. We acknowledge that the USPSTF, ADA and AACE recommend diabetes screening frequency screening of once every 3 years.[267] [268] [269] We propose expanding the frequency limitations for diabetes screening to twice in a 12-month period under the theory that additional flexibility in screening frequency will remove barriers and empower clinicians to apply screening test by multiple types of tests or with increased frequency where the circumstances of the patient demonstrate a medical necessity. We look forward to further consultation with organizations through the public notice and comment rulemaking process and invite public comment on our proposal.

We propose to simplify the regulatory definitions of ''diabetes'' for the purpose of diabetes screening at § 410.18(a), MNT at § 410.130 and DSMT at § 410.140. In all three instances, we propose to remove the codified clinical test requirements from the definition of ''diabetes'' and keep a shorted version of the existing definition that would define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. We now recognize that regulatorily codifying clinically specific test criteria into the regulatory definition of diabetes for screening, MNT and DSMT benefit reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. We believe that our proposal will empower practitioners to apply clinically accurate and appropriate criteria and that we can ensure certain safeguards through medical coding and claims processing instructions. By analogy, we consider that end stage renal disease (ESRD) is not described with specific clinical test criteria in section 226A and 1881 of the Act, nor in regulations at § 406.13. We generally believe that scientific advancements in understanding and measuring disease pathology outpace the lengthy and formal notice and comment rulemaking process. In the instance of diabetes screening, MNT and DSMT, the regulatory codification of clinical test criteria into disease definitions may not be necessary nor ideal. We note that even without clinical test criteria codified in the regulatory definitions of diabetes and pre-diabetes, a Medicare claim that includes a diagnosis of diabetes or pre-diabetes would still need to include appropriate coding, substantiation in the medical record and compliance with claims processing instructions from CMS and Medicare Administrative Contractors (MACs).

In the alternative, we considered not removing the clinical test criteria for the regulatory definitions of diabetes or removing the regulatory definition of pre-diabetes. We considered adding the HbA1c test criteria result of 6.5% or greater into the regulatory definition of diabetes for screening, MNT and DSMT and the HbA1c test criteria result of 5.7 percent to 6.4 percent to the regulatory definition of pre-diabetes for screening. The alternative would be consistent with our proposal to expand coverage of diabetes screening by adding the HbA1c test, and would also be consistent with clinical recommendations by the USPSTF [270] and the ADA.[271] However, we did not propose this alternative because, while currently clinically appropriate, we believed it would further, unnecessarily complicate the regulatory definition of diabetes and pre-diabetes. As noted earlier, we now recognize that regulatorily codifying clinically specific test criteria into the regulatory definition of ''diabetes'' and ''pre-diabetes'' for screening, and ''diabetes'' for the MNT and DSMT benefits reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit. We invite public comment on our proposal and alternative considered.

We believe that our proposal to expand and simplify coverage for diabetes screening aligns with the administration's strategic pillar to advance health equity by addressing the health disparities that underlie our health system. The August 2021 updated USPSTF final recommendation statement reads, ''The prevalence of diabetes is higher among American Indian/Alaska Native (14.7 percent), Asian (9.2 percent), Hispanic/Latino (12.5 percent), and non-Hispanic Black (11.7 percent) persons than among non-Hispanic White (7.5 percent) persons. Disparities in diabetes prevalence are the result of a variety of factors. A large body of evidence demonstrates strong associations between prevalence of diabetes and social factors such as socioeconomic status, food environment, and physical environment. The higher prevalence of diabetes in Asian persons may be related to differences in body composition. A difference in body fat composition in Asian persons results in underestimation of risk based on BMI thresholds used to define overweight in the US.'' [272] The HbA1c test does not require fasting or drinking an unappetizing glucose solution. Expanding coverage for diabetes screening to include the HbA1c test will reduce screening burdens for a disease that disproportionally impacts minority and disadvantaged populations. In addition, earlier identification of diabetes and prediabetes among minorities and disadvantaged persons may lead to improved diabetes control

[266] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes.*

[267] *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes.*

[268] *https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.*

[269] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes#bootstrap-panel--10.*

[270] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes#bootstrap-panel--6.*

[271] *https://diabetesjournals.org/care/article/43/Supplement_1/S14/30640/2-Classification-and-Diagnosis-of-Diabetes.*

[272] USPSTF website: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes.*

and reduce its complications, which currently occur disproportionately in those groups.

5. Summary

In summary, we propose to exercise our authority in sections 1861(yy) of the Act to: (1) expand coverage of diabetes screening tests to include the HbA1c test; (2) expand and simplify the frequency limitations for diabetes screening; and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT. We believe our proposals will expand access to quality care and improve health outcomes for patients through prevention, early detection, and more effective treatment. We recognize that expanded access and appropriate utilization of diabetes screening is critical to mitigating and avoiding downstream health complications that significantly impact beneficiary wellbeing, as well as being costly and burdensome to the healthcare system. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) website states, ''diabetes can cause serious health problems, such as heart disease, stroke, and eye and foot problems. Prediabetes also can cause health problems. The good news is that type 2 diabetes can be delayed or even prevented. The longer you have diabetes, the more likely you are to develop health problems, so delaying diabetes by even a few years will benefit your health.'' [273] The U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation recently published a Report to Congress on the Affordability of Insulin that included a number of generalized findings on downstream impacts of serious diabetes related complications on health care use.[274] Their findings include:

- In 2019, there were 8.7 million hospitalizations related to diabetes overall. About 71 percent were a result of the patient going to the emergency department. Ten percent of the 8.7 million hospitalizations had a principal diagnosis of diabetes.
- About 83 percent of hospitalizations occurred among patients living in communities in the bottom 50 percent of U.S. income, measured using median household income of the patient's zip code, underscoring the need for affordable access to treatment for diabetes.
- We also examined potentially avoidable hospitalization costs for Medicare and Medicaid beneficiaries with diabetes, specifically examining the costs for patients with amputations and ketoacidosis. For Medicare in 2020, total costs were $3.8 billion for amputations, $5.6 billion for ketoacidosis, and another $1.0 billion for patients with both. Medicare paid more than 90 percent of overall costs, covering $3.5 billion for amputations, $5.2 billion for ketoacidosis, and $936 million for hospitalizations involving both.

M. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Previous Regulatory Action

In the CY 2021, CY 2022, and CY 2023 PFS final rules, we finalized policies for the CMS EPCS Program requirements specified in section 2003 of the SUPPORT Act (Pub. L. 115–271, October 24, 2018). We refer readers to 85 FR 84802 through 84807, 86 FR 65361 through 65370, and 87 FR 70008 through 70014 for the details of the statutory requirements and those finalized policies. Specifically, in the CY 2022 PFS final rule, we extended the date of compliance actions to no earlier than January 1, 2023 and, for prescribers writing Part D controlled substances prescriptions for beneficiaries in long-term care (LTC) facilities, January 1, 2025 (86 FR 65364 and 65365). We also finalized a proposal requiring prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366); finalized multiple proposals related to the classes of exceptions specified by section 2003 of the SUPPORT Act (86 FR 65366 through 65369); and finalized our proposal to limit compliance actions with respect to compliance through December 31, 2023 to a non-compliance notice (86 FR 65370).

In the CY 2023 PFS final rule (87 FR 70012 through 70013), we extended the existing non-compliance action of sending notices to non-compliant prescribers, which we had finalized for the CY 2023 CMS EPCS Program implementation year (January 1, 2023 through December 31, 2023), to the CY 2024 Program implementation year (January 1, 2024 through December 31, 2024). We also finalized a change to the data sources used to identify the geographic location of prescribers for purposes of the recognized emergency exception at § 423.160(a)(5)(iii) (87 FR 70011 through 70012) and finalized our proposal to use the Prescription Drug Event (PDE) data from the current evaluated year instead of the preceding year when CMS determines whether a prescriber qualifies for an exception based on issuing 100 or fewer Part D controlled substance prescriptions per calendar year (87 FR 70009 through 70011).

2. CMS EPCS Program Terminology

In the CY 2021, CY 2022, and CY 2023 PFS final rules (85 FR 84802 through 84807, 86 FR 65361 through 65370, and 87 FR 70008 through 70013), we used various terminology to describe aspects of the requirements for EPCS. In order to provide consistency and clarity throughout the CMS EPCS Program and future rules, we will use the following terms going forward.

- *CMS EPCS Program.* We will refer to the program requirements for EPCS at § 423.160(a)(5) as the ''CMS EPCS Program.'' We believe this provides an appropriate distinction from the prescriber's act of electronically submitting individual prescriptions for controlled substances, which is also referred to as EPCS.
- *Non-compliance action or action for non-compliance.* We will use ''non-compliance action'' or ''action for non-compliance'' to refer to a consequence for not meeting the CMS EPCS Program compliance threshold, as described at § 423.160(a)(5), after exceptions have been applied.
- *Measurement year.* When we refer to ''measurement year,'' we mean the time period (beginning on January 1 and ending on December 31 of each calendar year) during which data is collected to calculate outcomes for the CMS EPCS Program. In prior rules, we have used the term ''current year'' or ''evaluated year,'' but moving forward we will use the term ''measurement year.''
- *Compliance threshold.* For the CMS EPCS Program, ''compliance threshold'' is the requirement at § 423.160(a)(5) that prescribers must conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, after exceptions, each measurement year.
- *Compliance analysis period.* The ''compliance analysis period'' is the time period after the measurement year where data is analyzed to determine whether prescribers have met the compliance threshold for the CMS EPCS Program.

[273] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, website: *https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-type-2-diabetes.*

[274] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Report on the Affordability of Insulin. December 16, 2022. *https://aspe.hhs.gov/reports/insulin-affordability-rtc.*

• *Notification period.* The ''notification period'' is the time period during which we notify a prescriber of the prescriber's initial compliance status and any associated review or waiver process that may be available prior to CMS determining the prescriber's final compliance status.

• *Measurement cycle.* The ''measurement cycle'' is generally a period of 24 months, consisting of a measurement year, the compliance analysis period, and the notification period.

3. Standard for CMS EPCS Program

a. Updates to the NCPDP Standards

In the CY 2021 PFS final rule (85 FR 84804), we finalized a requirement for Part D prescribers to use the NCPDP SCRIPT standard version 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances covered under Medicare Part D. In the CY 2021 PFS proposed rule, we had stated our belief that because prescribers were already required to use this standard when e-prescribing for covered Part D drugs for Part D eligible individuals, prescribers should use this same standard when e-prescribing controlled substances (85 FR 50261).

On December 27, 2022, as part of the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications proposed rule (herein referred to as the ''CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule'') (87 FR 79550), we proposed to update provisions related to e-prescribing standards at § 423.160(b), including, after a transition period, requiring the NCPDP SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for covered Part D drugs for Part D eligible individuals. The CY 2024 Medicare Advantage and Part D Policy and Technical Changes final rule appeared in the April 12, 2023 **Federal Register** (88 FR 22120). In the final rule, we did not address comments received on the provisions of the proposed rule related to e-prescribing standards as these provisions were not finalized in the final rule. Rather, we will address provisions of the proposed rule that we did not finalize at a later time, such as in possible future rulemaking, as appropriate.

As stated in the CY 2021 PFS proposed rule (85 FR 50261), our intent with the CMS EPCS Program is for prescribers to use the same version of the NCPDP SCRIPT standard for their electronic prescribing of Schedule II–V controlled substances that are Part D drugs as for other electronic prescribing for Part D eligible individuals. Although we finalized the NCPDP SCRIPT standard version 2017071 as the standard in the CY 2021 PFS final rule, we want to clarify that, based on the existing regulatory text at § 423.160(a)(5), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. This is based on the requirement at § 423.160(a)(5) that prescribers conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of § 423.160. Therefore, any proposals from the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule to standards at § 423.160(b) that are finalized will apply to electronic prescribing for the CMS EPCS program as well.

b. Standards for Same Legal Entity

In the CY 2022 PFS final rule (86 FR 65366), we finalized an exception at § 423.160(a)(5)(i) for prescriptions issued where the prescriber and dispensing pharmacy are the same entity (hereafter called the same entity exception). We stated our belief that a requirement to use the NCPDP SCRIPT standard version 2017071 within a closed system could increase costs and the rate of performance errors, such as data corruption and patient matching errors, which we understand often happens when a unified database is split into a transaction system that relays information to and from the same entity.

As we have implemented the same entity exception, our experience has been that the Prescription Drug Event (PDE) data, which we use for CMS EPCS Program compliance calculations, does not have a field that consistently and accurately identifies prescribers and dispensing pharmacies that are part of the same entity, making it impossible to exclude these prescriptions from the compliance calculations using PDE data. Additionally, we realized that we can include prescriptions where the prescriber and dispensing pharmacy are the same entity without triggering the concerns that led us to us to finalize the same entity exception, if we remove the requirement to use the NCPDP SCRIPT standard listed in § 423.160(b), as described below.

Medicare Part D has an existing electronic prescribing regulation that permits the use of either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the beneficiary are part of the same legal entity while still maintaining the requirement for e-prescribing. The Medicare Program; E-Prescribing and Prescription Drug Program final rule (70 FR 67581), which appeared in the November 7, 2005 **Federal Register**, codified at § 423.160(a)(3)(ii), that either HL7 messages or the NCPDP SCRIPT Standard could be used when all parties to a transaction are, for example, employed by and part of the same legal entity. We subsequently finalized a proposal to move the provision to § 423.160(a)(3)(iii) in the CY 2008 PFS final rule (72 FR 66405).

We propose to integrate this regulation into the CMS EPCS Program, as it provides alignment across electronic prescribing policies for prescriptions prescribed and dispensed within the same legal entity without forcing these entities to adopt the NCPDP SCRIPT standard for such transmittals. With this proposal, prescribers in the same legal entities as the dispensing pharmacy would have multiple methods to conduct internal electronic transmittals for Schedule II, III, IV, and V controlled substances that are Part D drugs, as permitted in § 423.160(a)(3)(iii). Therefore, we believe that these prescribers' prescriptions can be included in the CMS EPCS Program compliance calculation so long as prescribers' electronic prescriptions are transmitted consistent with the exemption in § 423.160(a)(3)(iii).

With this proposal, we would no longer need to separately identify and apply different methodologies based on whether the prescriber and dispensing pharmacy are the same entity. We would identify electronic prescriptions for Schedule II–V controlled substances that are Part D drugs using the Prescription Origin Code data element in the PDE record, where a value of three indicates electronic transmission. Additionally, this proposal would expand the available standards for prescribers that are within the same legal entities as the dispensing pharmacy under the CMS EPCS Program, as defined by the Medicare Program; E-Prescribing and Prescription Drug Program final rule (70 FR 67581),

by cross-referencing the standards at § 423.160(a)(3)(iii), which broadens the requirements of the e-prescribing standard that can be used to meet CMS EPCS Program requirements. We believe that by aligning with the regulation at § 423.160(a)(3)(iii), we are advancing e-prescribing standardization and addressing potential concerns about burdening prescribers within the same legal entity, including workflow and data errors.

Therefore, to address our data limitations and also to provide flexibility where prescriptions are transmitted within the same legal entity, we are proposing to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program requirements and to redesignate paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively. We also propose to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5). Under this proposed change, prescriptions that are prescribed and dispensed within the same legal entity would be included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5), and prescribers will not be exempt from the requirement to prescribe electronically at least 70 percent of their Schedule II–V controlled substances that are Part D drugs—but such prescriptions would only have to meet the applicable standards in § 423.160(b) subject to the exemption in § 423.160(a)(3)(iii).

We seek comment on the proposals to remove the same entity exception and expand the available standards for same legal entities within the CMS EPCS Program.

4. Definition of Prescriptions for Compliance Calculation

In the CY 2022 PFS final rule, we finalized the compliance threshold requirement for the CMS EPCS Program such that prescribers are required to prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, except in cases where an exception or waiver applies (86 FR 65366). Additionally, we indicated that the compliance threshold for each prescriber would be calculated by examining PDE data at the end of the measurement year and dividing the number of Part D controlled substances that were e-prescribed by the total number of Part D controlled substance prescriptions (excluding from both the numerator and denominator any prescriptions issued while a prescriber falls within an exception or is subject to a waiver) (86 FR 65365). Previously, we did not define how prescriptions with multiple fills would affect the compliance threshold calculation. We are now proposing to specify how the compliance threshold is affected by multiple fills within the same year.

For purposes of CMS EPCS Program, we will count unique prescriptions in the measurement year using the prescription number assigned by the pharmacy and included in the Part D claims data. All prescriptions, regardless of how they are transmitted, may include a number of refills so that the pharmacy may provide additional fills of the prescribed medication without the need for a new prescription from, or visit to, a prescriber. Refills are not separately transmitted prescriptions; they are documented as part of the original prescription transmittal, which includes any refills issued against the original prescription (by the pharmacy). However, renewals of prescriptions (such as those for maintenance medications) require prescribers to generate a new prescription along with a new set of refills. Because of this distinction, we will count renewals as an additional prescription in the CMS EPCS Program compliance threshold calculation, and we will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year.

We believe, if we were to include every fill in the compliance threshold calculation, an increased burden could be placed on small prescribers, as they would potentially no longer qualify for the small prescriber exception at § 423.160(a)(5)(ii) (which we propose to be redesignated to § 423.160(a)(5)(i), as described in section III.M.3.b. of this rule). If we were to count every single fill, preliminary analysis of 2021 Part D data shows that approximately 23,000 prescribers would no longer qualify for the small prescriber exception and that approximately 6,900 additional prescribers would be considered non-compliant. For this reason, we would count only the unique prescriptions in the measurement year for the purposes of CMS EPCS Program compliance threshold calculations.

5. Updates to CMS EPCS Program Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances

a. Background

In the CY 2022 PFS final rule (86 FR 65367 through 65368), we finalized two exceptions related to exceptional circumstances that may prevent prescribers from being able to conduct EPCS. The first exception, codified at § 423.160(a)(5)(iii), is for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. Prescribers in a geographic area of an emergency or disaster declared by a Federal, State, or local government entity are excluded from the CMS EPCS Program requirements. In the CY 2023 PFS final rule (87 FR 70012), we modified the exception to use the prescriber's PECOS address or, in situations where a prescriber does not have a PECOS address, the prescriber's address in the National Plan and Provider Enumeration System (NPPES) data, to determine whether the exception at § 423.160(a)(5)(iii) is applicable.

The second exception, codified at § 423.160(a)(5)(iv), is for prescribers who request and receive from CMS a waiver, which we grant to prescribers who are facing extraordinary circumstances that prevent them from electronically prescribing a controlled substance to a Part D beneficiary, but who are not in an emergency or disaster area. We defined ''extraordinary circumstance'' for purposes of this exception to mean a situation, other than an emergency or disaster, outside of the control of a prescriber that prevents the prescriber from electronically prescribing a controlled substance to a Part D beneficiary (86 FR 65367).

In this rule, we are proposing to further modify the recognized emergency exception and extraordinary circumstances waiver (which we propose to be codified at § 423.160(a)(5)(ii) and (iii), respectively, as described in section III.M.3.b. of this rule). We are proposing to modify the rules for when these exceptions apply by enabling prescribers to apply for waivers in times of an emergency and disaster and by limiting the emergencies or disasters that would trigger the recognized emergency exception. Additionally, we are proposing to modify the duration of both exceptions and proposing timing requirements for submitting a waiver application.

b. Updating the Circumstances Applicable for the Recognized Emergency and Extraordinary Circumstances Waiver Exceptions

Our current exception for recognized emergencies applies to all prescribers with an address in PECOS, or alternatively in NPPES, in the geographic area of an emergency or

disaster declared by a Federal, State, or local government entity. As we have implemented this exception, we realize there may be unintended consequences to our existing policy. First, while we can identify emergencies recognized by the Federal Emergency Management Agency (FEMA) or pandemics recognized by the Department of Health and Human Services (HHS), we may not be able to identify every local or state emergency. Because we excluded emergencies and disasters from our extraordinary circumstances waiver policy, some prescribers may not be able to receive an exception for an emergency or disaster we did not identify. Second, we realize that not every emergency may impact the ability of prescribers to conduct EPCS, and thus it may not be appropriate to automatically apply the exclusion to all prescribers in the affected geographic area of some emergencies. Third, we realized that some of our policies do not align with other emergency policies of CMS programs for quality reporting and performance. Therefore, in order to address these concerns, we looked to the Quality Payment Program Merit-based Incentive Payment System (MIPS) automatic policy for extreme and uncontrollable circumstances and to the extraordinary circumstances exceptions (ECE) for many of our quality reporting and value-based purchasing programs for hospitals and other types of facilities to see other examples of when we apply automatic exceptions versus when we ask clinicians or facilities to apply for a waiver.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38410) and CY 2018 OPPS/ASC final rule (82 FR 52584), we worked to align common processes for our ECE policies across many of our quality programs including the Hospital IQR Program, Hospital OQR Program, IPFQR Program, ASCQR Program, and PCHQR Program, as well as the Hospital VBP Program, HAC Reduction Program, and the Hospital Readmissions Reduction Program. Using the Hospital IQR Program as an example, generally, CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital (42 CFR 412.140(c)(2)). A hospital may submit such a request in the form and manner described on *QualityNet.org.* CMS may also grant an exception to one or more hospitals that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data; or if CMS determines that an extraordinary circumstance, such as an act of nature (for example, hurricane), has affected an entire region or locale (*see* § 412.140(c)(2)(ii) and 76 FR 51651). We stated that if we make the determination to grant an ECE to hospitals in a region or locale, we would communicate this decision through routine communication channels (76 FR 51652).

Separately, in the context of clinicians participating in MIPS, CMS established another ECE policy. In the Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year (CY 2018 Quality Payment Program final rule), we adopted in an interim final rule with comment period an automatic extreme and uncontrollable circumstances policy for one performance period due to several hurricanes (82 FR 53895 through 53900). In discussing the triggering events for this policy (82 FR 53897), we stated that we have discretion not to require MIPS eligible clinicians to submit an application for reweighting the performance categories in cases where an extreme and uncontrollable circumstance, such as an act of nature (for example, hurricane), affects an entire region or locale. We noted that we anticipate the types of events that could trigger this policy would be events designated by the Federal Emergency Management Agency (FEMA) as major disasters or a public health emergency declared by the Secretary, although we will review each situation on a case-by-case basis. We also noted our intention to align the automatic extreme and uncontrollable circumstance policy with the ECE policies for other Medicare programs such that events that trigger ECE policies would also trigger the automatic extreme and uncontrollable circumstance policy (82 FR 53897). In the CY 2019 PFS final rule (83 FR 59875), we finalized a similar policy for all future years, which we codified at § 414.1380(c)(2)(i)(A)(*8*) and (C)(3).

We believe that it would be beneficial to interested parties for the CMS EPCS Program to have a similar policy as it relates to applying for an exception versus having an automatic exception for all prescribers in an affected region. This would streamline communications across CMS programs, as well as ensure that CMS can, where appropriate, except all prescribers for an appropriate circumstance beyond their control, including disasters or emergencies. In order to facilitate this transition, for the waiver exception at § 423.160(a)(5)(iv) (which we propose to codify at § 423.160(a)(5)(iii), as described in section III.M.3.b. of this rule), we are proposing to modify the definition of ''extraordinary circumstance'' to mean a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II–V controlled substance that is a Part D drug. This updated definition would drop the restriction ''other than an emergency or disaster,'' that we previously included when discussing this exception. This modification would allow prescribers the ability to request a waiver regardless of whether we trigger the recognized emergency exception.

Additionally, we are proposing to modify the recognized emergency exception at § 423.160(a)(5)(iii) (which we propose to codify at § 423.160(a)(5)(ii), as described in section III.M.3.b. of this rule) so that CMS will identify which events trigger the recognized emergency exception. We believe the ability to identify triggering events will allow us to ensure that the emergency affects widespread EPCS functionality. In applying this determination of which emergencies or disasters would trigger this exception, we would review each emergency situation on a case-by-case basis but would generally look to events designated as a FEMA major disaster or a public health emergency declared by the Secretary. We also intend to align the determination of the emergency exception with the MIPS automatic extreme and uncontrollable circumstances policy, such that events that would trigger this policy, in most instances, would also qualify under the CMS EPCS Program exception for recognized emergencies. We expect any deviation from MIPS automatic extreme and uncontrollable circumstances policies would be rare and only in circumstances which may cause disruption for MIPS performance but should not affect a prescriber's ability to electronically prescribe Schedule II–V controlled substances that are Part D drugs, or vice versa.

We would inform prescribers of which emergencies or disasters qualify for the exception, as determined by CMS, using normal communication channels such as listservs and the CMS EPCS Program website.

We invite public comment on the proposals related to circumstances applicable for the recognized emergency and extraordinary circumstances waiver exceptions.

c. Duration of Recognized Emergency Exceptions

In the CY 2022 PFS final rule (86 FR 65367), we clarified that the recognized emergency exception would be applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring. In an effort to continue aligning the CMS EPCS Program with the Quality Payment Program, we propose that, as a default, prescribers impacted by the CMS EPCS Program recognized emergency exception at § 423.160(a)(5)(iii) (which we propose to codify at § 423.160(a)(5)(ii), as described in section III.M.3.b. of this rule) would be excepted for the entire measurement year, and not just for the duration of the emergency. We believe this would protect prescribers who may not be able to monitor their compliance status over multiple periods of time.

We seek comment on the proposed duration for exceptions due to recognized emergencies.

d. Duration and Timing of Extraordinary Circumstances Waiver Exception

In the CY 2022 PFS final rule (86 FR 65367 through 65368), we finalized an attestation process for prescribers to request a waiver.[275] In this rule, we are not proposing any modifications on the information needed to request a waiver, but we are proposing the timeframe that would be covered by a waiver that is authorized under the CMS EPCS Program and the timing of waiver requests.

Section 1860D–4(e)(7)(B)(iii) of the Act, as added by section 2003 of the SUPPORT Act, refers to a waiver or a renewal thereof for a period of time, not to exceed one year, as determined by the Secretary. We propose that approved waivers for the CMS EPCS Program would apply to the entire measurement year. Prescribers who receive a waiver and continue to experience exceptional circumstances that extend beyond December 31 of a measurement year would be required to complete a new waiver application for the subsequent measurement year.

In the CY 2022 PFS proposed rule (86 FR 39332), we signaled that we would include more information about the waiver process in subsequent rulemaking. One issue that was not clearly defined is the timing of when a prescriber can request a waiver. In the CY 2022 PFS final rule (86 FR 65370), we finalized that we would notify prescribers that they are violating the EPCS requirement with information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver. We are now proposing that a prescriber has a period of 60 days from the date of the notice of non-compliance to request a waiver. Approved waivers would apply to prescriptions written by a prescriber for the entire measurement year, and the waiver would expire on December 31 of the applicable measurement year.

We seek comment on the proposed waiver duration and the proposal for the timing and process of applying for waiver in cases of extraordinary circumstances.

6. Actions for Non-Compliance

In the CY 2022 PFS final rule (86 FR 65370), we limited compliance actions with respect to compliance from January 1, 2023 through December 31, 2023, to a non-compliance notice sent to prescribers who are violating the CMS EPCS Program requirement. In the CY 2023 PFS final rule (87 FR 70013), we extended the existing compliance action of sending notices to non-compliant prescribers from the CY 2023 CMS EPCS Program implementation year (January 1, 2023 through December 31, 2023) to the CY 2024 EPCS Program implementation year (January 1, 2024 through December 31, 2024). The content of the notices will remain unchanged and continue to consist of a notice to prescribers that they are violating the CMS EPCS Program requirements, information about how they can come into compliance, the benefits of EPCS, and a link to the CMS EPCS Program dashboard where the prescriber may request a waiver and provide information as to why they are not conducting EPCS.

We propose to continue the practice of issuing a prescriber notice of non-compliance as a non-compliance action for subsequent measurement years. As stated in the CY 2023 PFS final rule (87 FR 70013), we believe prescriber use of EPCS encourages the use of interoperable technology, produces a verifiable and traceable history, prevents fraud and abuse, and reduces burden. We believe that continuing to send non-compliance notices would support increased EPCS adherence and encourage increased EPCS adoption rates, which could be more effective than imposing more restrictive non-compliance actions or penalties that may increase burden on prescribers.

In the CY 2023 PFS proposed rule (87 FR 46240 through 46241), we solicited ideas of possible non-compliance actions with the goal of identifying one that would be operationally feasible (for example, can be accomplished without requiring modifications to the data available through the PDE file) and support the nation's ongoing fight against drug abuse and diversion without adding administrative burden to prescribers or hindering beneficiary access to needed medications. We did not receive a large number of comments. However, we did receive one comment noting that non-compliance alone is not a definitive indicator of fraud, waste, or abuse. We agree with the commenter that non-compliance alone is not a definitive indicator of fraud, waste, or abuse; however, we maintain that one risk to public safety is potential fraud, waste, and abuse and intend that a prescriber's non-compliance under the CMS EPCS program may be considered in our processes for assessing potential fraud, waste, and abuse.

We may use this information in our processes for assessing potential fraud, waste, and abuse, which, in some instances, could result in a referral to law enforcement or revocation of billing privileges, in the event that evidence of fraud, waste, or abuse is present. At this time, we believe the risk of fraud, waste, or abuse can be mitigated without the need for further penalties for CMS EPCS program non-compliance. Literature suggests a correlation between use of EPCS and reduction in fraud, waste, and abuse related to opioid prescriptions.[276] [277] Prescriber use of EPCS is directly related to improving prescription security, decreasing prescription forgery, and reducing the overall chance of fraud and alteration associated with paper prescribing.[2] Also notable are studies demonstrating reductions in opioid overdoses when EPCS use is increased and general findings that e-prescribing can improve coordination of care, reduce fraud and abuse, and contribute to public health safety.

Although we are not proposing further non-compliance actions beyond the extension of sending notices at this time, we will continue to evaluate compliance and prescriber performance

[275] The waiver application is currently going through the Paperwork Reduction Act approval process under the document identifier CMS–10834, and the proposed collection comment request appeared in the March 10, 2023 **Federal Register** (88 FR 15037).

[276] Achar, Suraj, et al. ''Adoption and Increased Use of Electronic Prescribing of Controlled Substances.'' *Journal of Medical Regulation,* Federation of State Medical Boards, 27 Aug. 2021, *https://doi.org/10.30770/2572-1852-107.2.8.*

[277] Abuok, Rahi, and David Powell. ''Can Electronic Prescribing Mandates Reduce Opioid-Related Overdoses?'' Science Direct, JOURNAL of ECONOMICS & HUMAN BIOLOGY, Elsevier B.V., 14 Apr. 2021, *https://doi.org/10.1016/j.ehb.2021.101000.*

under the CMS EPCS Program and will consider whether to propose changes in future years. We seek public comment on our proposal to continue the action of sending notice to prescribers who are identified as non-compliant.

N. Proposed Changes to the Regulations Associated With the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS)

1. Background on Ambulance Services

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414 subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments in § 414.610(c)(5)(i) and three temporary add-on payments to the base rate and/or mileage rate, which are discussed in the next section of this proposed rule.

Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, enacted July 15, 2009) (MIPPA), amended section 1834(l)(13) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13) of the Act have been extended several times. Most recently, division FF, section 4103 of the CAA, 2023 (Pub. L. 117–328, December 29, 2022) amended section 1834(l)(13) of the Act to extend the payment add-ons through December 31, 2024. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2025. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743), the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072) and the CY 2019 PFS final rule with comment period (83 FR 59681 through 59682)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 8, 2003) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, division FF, section 4103 of the CAA, 2023 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2024. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2025 where transportation originates in a qualified rural area. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744), the CY 2016 PFS final rule with comment period (80 FR 71072) and the CY 2019 PFS final rule with comment period (83 FR 59682)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2024, and does not require any substantive exercise of discretion on the part of the Secretary.

3. Medicare Ground Ambulance Data Collection System

a. Background

Section 50203(b) of the BBA of 2018 added paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers (ground ambulance organizations) to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground

ambulance services. Section 1834(l)(17)(B)(i) of the Act required the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system. Section 1834(l)(17)(D) of the Act required that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. Division P, section 311 of the CAA, 2022 (Pub. L. 117–103) amended section 1834(l)(17)(F)(i) of the Act to delay the deadline for MedPAC to submit its report to Congress on the ground ambulance data collection system study until the second June 15th following the date the Secretary transmits data for the first representative sample of ground ambulance organizations. Section 1834(l)(17)(I) of the Act states that the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.) does not apply to the collection of information required under section 1834(l)(17) of the Act.

In the CY 2020 PFS final rule (84 FR 62864 through 62897), we implemented section 1834(l)(17) of the Act and codified regulations governing data reporting by ground ambulance organizations at §§ 414.601, 414.605, 414.610(c)(9), and 414.626. We also finalized a data collection system that collects detailed information on ground ambulance provider and supplier characteristics including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare Ground Ambulance Data Collection Instrument, via a web-based system. We refer the reader to our CY 2020 PFS final rule (84 FR 62864 through 62897) for more specifics on the establishment of the Medicare Ground Ambulance Data Collection System.

In the CY 2022 PFS final rule (86 FR 65306 through 65317), we finalized a number of updates to the Medicare Ground Ambulance Data Collection System, including: (1) a new data collection period beginning between January 1, 2023, and December 31, 2023, and a new data reporting period beginning between January 1, 2024, and December 31, 2024, for selected ground ambulance organizations in Year 3; (2) aligning the timelines for the application of penalties for not reporting data with our new timelines for data collection and reporting and a notice that the data collected will be publicly available beginning in 2024; and (3) revisions to the Medicare Ground Ambulance Data Collection Instrument that include better accounting for labor hours across different categories of personnel and better distinguishing between accrual and cost basis accounting methodologies. We refer the reader to our CY 2022 PFS final rule (86 FR 65306 through 65317) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

In the CY 2023 PFS final rule (87 FR 70014) we finalized a series of changes to the Medicare Ground Ambulance Data Collection System. First, we finalized our proposal to update our regulations at § 414.626(d)(1) and (e)(2) to provide the necessary flexibility to specify how ground ambulance organizations should submit hardship exemption requests and informal review requests, including to our web-based portal once that portal is operational. Second, we finalized our proposed changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument to reduce burden on respondents, improve data quality, or both. We refer the reader to our CY 2023 PFS final rule (87 FR 70014) for more specifics on the revisions to the Medicare Ground Ambulance Data Collection System.

b. Proposed Revisions to the Medicare Ground Ambulance Data Collection Instrument

As described in the CY 2022 PFS final rule (86 FR 65307) and the CY 2023 PFS Final Rule (87 FR 70014), we made several changes to the instrument instructions and questions to improve clarity and reduce burden for respondents. A printable version of the current instrument instructions and questions is available in English and Spanish on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Ground-Ambulance-Services-Data-Collection-System.*

We continue to receive ad hoc questions and feedback related to the Medicare Ground Ambulance Data Collection System and the Medicare Ground Ambulance Data Collection Instrument via four primary channels. First, we receive email and other written communication from ground ambulance organizations via the CMS Ambulance Data Collection email inbox (*AmbulanceDataCollection@cms.hhs.gov*) and through other channels (for example, inquiries sent by organizations to Medicare Administrative Contractors (MACs) and then forwarded to CMS). These emails and other communications often include questions seeking clarification of instrument questions and their applicability to specific ground ambulance organization scenarios and context. We continue to update a Medicare Ground Ambulance Data Collection System Frequently Asked Questions (FAQ) document with answers and the GADCS User Guide to commonly asked questions. These documents are available on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ambulancefeeschedule/ground-ambulance-services-data-collection-system.* Through review of questions and feedback, we identified some instances where a clarification to the instrument language itself will likely be more useful and less burdensome to respondents than having to respond with reference to the FAQ document, the GADCS User Guide, or to other resources. Second, we answer questions live from interested parties during webinars, dedicated question and answer sessions, and other educational sessions. As with the emailed questions described above, live question and answer exchanges sometimes identify opportunities for clarifying instrument language. Third, we have begun analyzing initial data responses submitted via the GADCS portal by selected organizations in Year 1 and Year 2. Findings from this initial analysis, including inconsistent response patterns, unusual combinations of responses across questions, and investigation of outlier results were helpful to identify some additional opportunities for clarification. Fourth, we continue to identify opportunities to clarify instructions and correct a small number of typos through the final development and launch of the web-based GADCS.

Based on information that we received via the four sources described above, we are proposing the following further changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on

respondents, improve data quality, or both.

1. Addressing Partial-Year Responses

Ground ambulance organizations selected to participate in the GADCS that are in operation for only part of their continuous, 12-month data collection period are, following the GADCS instructions, still required to collect and report data. However, there is not a field for these organizations to report that they were in operation, and therefore collecting data, for less than a full 12-month period via the GADCS. In these cases, we would not know that the costs, revenue, and utilization reported by these partial-year organizations are comparatively smaller than those reported by similar organizations in operation for an entire 12-month period. As a result, some statistics from analyses of GADCS data, for example total annual expenditures per ground ambulance organization, would be biased downward.

To address this limitation, we are proposing to add a response option to Section 2 (Organizational Characteristics), Question 1 which asks whether the selected national provider identifier (NPI) linked to the organization was used to bill Medicare for ground ambulance services during its data collection period. The current response options are ''Yes (1)'' and ''No (0)''. We propose to split the existing ''Yes (1)'' response into two separate responses, one reading ''Yes, throughout the organization's continuous, 12-month data collection period (1)'' and ''Yes, but for only part of the organization's continuous, 12-month data collection period (2).'' The ''No (0)'' response would not change. Respondents from organizations that billed for ground ambulance services during part of, but not all of, its continuous, 12-month data collection period, would select ''Yes, but for only part of the organization's continuous, 12-month data collection period (2)''. Those that did so would be prompted to enter the date they started and/or stopped operations during the continuous, 12-month data collection period in a pop-up box, followed by an instruction to proceed through the remainder of the GADCS reporting process.

Organizations selecting ''Yes, throughout the organization's continuous, 12-month data collection period (1)'' would proceed through the rest of the GADCS reporting process as do respondents answering ''Yes (1)'' to this question currently. Organizations selecting ''No (0)'' would, as is currently the case, be prompted with several follow-up questions which result in either outreach to the GADCS helpdesk for assistance if the listed NPI does not match their organization, or if they answer that none of the scenarios in the follow-up questions apply, or the completion of the organization's data reporting requirement.

This approach allows CMS to understand when reported costs, revenue, and utilization are measured over a period of time less than a full 12 months and, if necessary, to adjust partial-year responses so that they are more comparable to most responses that will cover a continuous full 12-month data collection period. Furthermore, we believe this approach will reduce confusion and burden for organizations in operation for only part of their 12-month data collection periods.

We invite comments on this proposal to address partial-year responses.

2. Programming Logic for Hospitals and Other Medicare Providers of Services

Section 2 of the GADCS printable instrument includes a programming note after Question 9 reading: ''For the remainder of the data collection instrument, instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that answer Section 2, Question 7 = ''a'' or ''b'' OR Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b.'' The intent of this programming note is to ensure questions in Section 7 (Labor Costs) present instructions and response fields appropriate to organizations with staff having both ground ambulance and fire, police, or other public safety responsibilities. In other words, a for-profit, ground ambulance-only organization should not be asked whether they have ground ambulance staff with fire, police, or other public safety responsibilities, while a fire department-based ground ambulance organization should.

Section 2, Question 8 asks whether organizations reporting to be fire department-based (response ''a'' in Section 2, Question 7), police or other public safety department-based (response ''b'' in Section 2, Question 7), or hospital or other Medicare provider of services-based (response ''d'' in Section 2, Question 7) share operational costs between ground ambulance and the respective other reported function. A programming note for Section 2, Question 8 states that the question should be asked of organizations responding a, b, or d to Section 2, Question 7. As a result, hospitals and other Medicare provider of services-based organizations responding ''d'' in Section 2, Question 7 are presented with Section 2, Question 8, and many may respond ''Yes'' to Section 2, Question 8. As discussed above, answering ''Yes'' to Section 2, Question 8 triggers the appearance of table columns in Section 7, Question 1 related to fire, police, and other public safety staff (''Section 2, Question 7 = ''a'' or ''b'' OR Question 8 = Yes (1) OR answer Question 9 = Yes (1) to one or both of a and b.)

As a result of these programming notes, many hospital-based organizations answering ''d'' to Section 2, Question 7 and ''Yes'' to Section 2, Question 8, and any options other than ''a'' or ''b'' in Section 2, Question 9 will see columns for fire, police, and other public safety staff in Section 7, Question 1, which was not intended. We believe that no ground ambulance organizations with this response pattern will have fire, police, or other public safety staff to report via the GADCS. Furthermore, we are concerned that this will result in confusion for hospital-based organizations.

We are proposing to change the programming note after Section 2, Question 9 to read as follows: ''. . . instructions and items related to fire, police, or other public safety department-based ground ambulance organizations are shown to organizations that: (A) answer Section 2, Question 7 = ''a'' or ''b'' AND answering Question 8 = Yes (1); OR, (B) answer Question 9 = Yes (1) to one or both of ''a'' or ''b''.'' This change to the programming logic will result in provider-based ground ambulance organizations seeing only two columns in Section 7, Question 1, one for paid and the other, if applicable, for volunteer staff, and not columns specific to staff with fire, police, or other public safety responsibilities.

We invite comments on this proposal to change the programming note after Section 2, Question 9 in the GADCS printable instrument.

3. Typos and Technical Corrections

We are proposing to make four corrections to the GADCS printable instrument.

- Section 2, Question 1a.ii is missing the word ''period'' after ''data collection'' in the text. Therefore, we are proposing the question to read as: ''The NPI was in operation during the data collection period but was not used during the data collection to bill Medicare for ground ambulance services.''
- Section 2, Question 3 in the printable instrument questions ''What is the name of your organization? For the remainder of the instrument, the term

''organization'' refers to the NPI for which we are requesting data. (enter name)'' while the web-based GADCS asks ''Is [ORGANIZATION NAME] the name of your organization? For the remainder of the instrument, the term 'organization' refers to the NPI for which we are requesting data. Yes (1)/ No (0).'' The web-based GADCS asks the question in this way because organization name is pre-populated in the system and not entered directly. We are proposing to change the language in the printable instrument to match the text in the web-based GADCS for consistency.

- Section 9.1 (Ground Ambulance Vehicle Costs), Question 5 current wording states ''Do not report ground ambulance acquisition costs related to an annual depreciation expense for the same ambulance'' which does not make sense. We are proposing Question 5 to read as: ''Do not report an acquisition cost and an annual depreciation expense for the same ground ambulance.''
- Section 9.2 (Other Vehicle Costs (Non Ambulance)), Question 5 current wording includes the same error as noted above for Section 9.1, Question 5, and also mistakenly refers to ground ambulances rather than non-ambulance vehicles: ''Do not report non-ambulance vehicle acquisition costs related to an annual depreciation expense for the same ground ambulance.'' We are proposing to change the question to read as: ''Do not report an acquisition cost and an annual depreciation expense for the same ground non-ambulance vehicle.''

We invite comments on these proposals related to GADCS typos and technical corrections.

O. Hospice: Changes to the Hospice Conditions of Participation

1. Background and Statutory Authority

We have broad statutory authority for most provider and supplier types to establish health and safety regulations, which includes the authority to establish health and safety requirements that advance health equity for underserved communities. Certain status explicitly gives CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an institution, while others give CMS the authority to prescribe regulations as may be necessary to carry out the administration of the program. Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248) (TEFRA), added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd)(2)(G) of the Act, the Secretary has established the Conditions of Participation (CoPs) that a hospice must meet to participate in Medicare and/or Medicaid, and these conditions are set forth at 42 CFR part 418. The CoPs apply to the hospice as an entity, as well as to the services furnished to each individual under hospice care. Under section 1861(dd), the Secretary is responsible for ensuring that the CoPs and their enforcement, are adequate to protect the health and safety of the individuals under hospice care. To implement this requirement, State survey agencies conduct surveys of hospices to assess their compliance with the CoPs.

The Consolidated Appropriations Act of 2023 (Pub. L. 117–328) (CAA 2023), was signed into law on December 29, 2022. Division FF, section 4121 of the CAA 2023 establishes a new Medicare benefit category for marriage and family therapist (MFT) services and mental health counselor (MHC) services furnished by and directly billed by MFTs and MHCs, respectively. Section 4121(b)(2) of CAA 2023 specifically adds these services to covered hospice care services under section 1861(dd)(2)(B)(i)(III) of the Act. In order to implement division FF, section 4121 of the CAA 2023, we are proposing to modify the requirements for the hospice CoPs at § 418.56 ''Interdisciplinary group, care planning and coordination of service'' and § 418.114 ''Personnel qualifications.'' This statutorily-required modification allows MHCs or MFTs to serve as members of the interdisciplinary group (IDG). Specifically, the CAA 2023 revised section 1861(dd) of the Act to state that the hospice interdisciplinary group is required to include at least one social worker, MFT, or MHC. In addition, we are proposing to modify the hospice personnel qualification at § 418.114(c) to also include qualifications for an MFT and an MHC.

2. Provisions of the Proposed Regulations

a. Updates to the Hospice CoPs To Permit Mental Health Counselors or Marriage and Family Therapists To Serve as Members of the Hospice Interdisciplinary Group (§§ 418.56 and 418.114)

The CAA 2023 established the new Medicare benefit category for MFT services and MHC services furnished by and directly billed by MFTs and MHCs.

In accordance with the statute, we propose to revise § 418.56(a)(1)(iii) to specify that the IDG must include a social worker (SW), an MFT, or an MHC. In addition, we believe that with the introduction of MHC and MFT into the hospice CoPs, it is important to also include these new disciplines into the personnel qualifications at § 418.114. Currently the requirement at § 418.114 establishes the requirements for several disciplines that work in hospices including but not limited to social worker, nurse and the therapist. In this rule, we are proposing to add both MHC and MFT to the provider requirements under 42 CFR subpart B, Medical and Other Health Services at §§ 410.54 and 410.53. Therefore, to avoid duplication and confusion between the CoP and the Medical and Other Health Services requirements, we are proposing to add both MHC and MFT to the requirements as new standards at § 418.114(c)(3) and (4) and reference the new requirements at §§ 410.54 and 410.53, respectively.

We note that the CAA 2023 specifically modified the statute to require the hospice interdisciplinary team to include at least one SW, MFT or MHC. However, we emphasize that each hospice patient and family are different in their needs and goals. Therefore, it is important for the hospice to assess and determine, along with the input from the patient and family, which care and services best align with the preferences and needs of the patient.

Furthermore, while we believe the role of the SW in hospice is unique and paramount to quality hospice care and services as the patient and their family approach the end of life, we also understand that some patients may benefit from the care and services of an MFT or MHC. However, the role and training of the SW, MFT and MHC vary greatly. As part of the SW role they offer unique support and services to the patient and family such as explaining what hospice care is and the role of the hospice team, assisting the patient and family in navigating the healthcare system, assisting patients and their family in understanding care options as they relate to patient goals and life circumstances, and identifying and working with the patient and their family to connect the patient to other services that may improve the patients quality of life. For example, a SW can make a referral for Meals on Wheels or link the patient to the Veteran's Administration (VA) and other benefits. The hospice SW can also guide the patient and family in applying for financial assistance or resources, such

as Medicaid, temporary assistance programs for energy or utilities, or county assistance programs. In addition, hospice SW are educated to assist patients in completing a living will and other advance directives, as well as educating patients about health care choices and assisting the patient and family in understanding the differences between wills and powers of attorney. They assist patients and family in deciding what environment is best for the patient to receive care and coordinate the many requirements for transferring the patient to the most appropriate care setting. For example, the SW will assist the patient as they transition from a hospital, assisted living facility or nursing home back to their home, or vice versa.

SW, MFTs and MHCs have some similar roles and responsibilities as they relate to counseling. All three of these providers can assist the patient and family with issues related to family dynamics, assessing situations, strengths, and the patient's support network. They can also assist patients and families with navigating the changes and challenges at the end of life including grief counseling and coping strategies to ease day to day emotions. The SW, MFT, or MHC can also provide age-appropriate education and emotional support for children and grandchildren. Some examples of this include providing activities that allow them to express their feelings appropriately, leading support groups, and providing individual, couples, and family counseling. The addition of the MFT and MHC may also be particularly beneficial for individuals living in rural areas who were previously not able to access these types of services.

We acknowledge that there are clear similarities and differences between SWs, MFTs and MHCs, ranging from offered services to experience to scope of practice. While the services SWs, MFTs, and MHCs provide are not interchangeable, each offers unique supports that may be valuable to the patient and family based on the situation. Therefore, the individual hospice patient's needs, preferences, and goals, should guide the determination of which member of the team (SW, MFT or MHC) serves as the member of the IDG for that patient. For example, if the patient's assessed needs relate to VA benefits, the SW may be the most appropriate provider to meet those needs. However, if the patient's assessed needs are related to unresolved issues with their spouse, it may be appropriate to have MHC or MFT provide services to the patient. We believe the ability for hospice patients to receive additional mental health services and supports as part of their hospice care may empower patients and their families in decision making, thus improving the overall health and safety of the patient.

b. Personnel Qualifications (§ 418.114)

As noted above, Division FF, section 4121 of the CAA 2023 requires CMS to permit an MHC or MFT to serve as members of the IDG. As discussed previously, we are proposing to modify the language at § 418.56 regarding the composition of the IDG to include MHCs and MFTs.

P. Request for Information: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

1. Background

The Clinical Laboratory Improvement Advisory Committee (CLIAC), CMS, interested parties, and State Agency (SA) surveyors have identified areas in the CLIA requirements that may need updating.

a. Histopathology

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578, October 31, 1988) regulations related to histopathology have not been updated since 1992. The current Histopathology requirements may not represent new innovations and technology performed in laboratories.

(1) Slide Preparation and Staining

Facilities only collecting or preparing specimens (or both) or only serving as a mailing service but not performing testing are not considered laboratories.[278] Slide staining and tissue processing have not been subject to the CLIA regulations. However, we received inquiries from interested parties stating that slide staining and tissue processing are an essential part of the testing process for histopathology. Absent these steps, the tissue cannot be prepared, mounted onto a slide, or accurately evaluated by a pathologist to make an assessment for diagnosis.

Slide staining in histopathology includes routine Hematoxylin and Eosin (H&E) staining, special stains, and immunohistochemical (IHC) stains. Routine slide staining in histopathology provides simple cellular identification and requires minimal steps with solutions, dyes, and clearing reagents (for example, Hematoxylin & Eosin stains, Giemsa stain). An individual trained under the supervision of a qualified technical supervisor can perform these staining techniques. An independent facility (for example, a processing center, that performs slide staining) is not required to hold a CLIA certificate. IHC stains are complex stains designed to identify specific antigens and targets within the cells. These targets can include ribonucleic acid (RNA) and deoxyribonucleic acid (DNA) specific reactivity. The U.S. Food and Drug Administration (FDA) has categorized instruments that perform automated IHC staining as high complexity. Therefore, individuals that perform IHC staining in a CLIA certified laboratory (for example, histotechnicians, histotechnologists, and pathology assistants) must meet the personnel requirements for facilities carrying out high complexity testing. The facility must also hold a CLIA certificate in the subspecialty of testing performed.

(2) Gross Tissue Examination Review

Testing in histopathology includes both gross tissue examination (macroscopic) and the microscopic evaluation of the stained slide(s) with evaluation and diagnostic interpretations, and the reporting of diagnostic findings by qualified personnel. Gross examination means the manipulation, orientation, and selection of the desired representative pieces of excised tissue from the total specimen received. This includes the physical examination and description, color, weight, measurements, and other characteristics of the tissue. Selected portions of the tissue are placed into a tissue cassette, subjected to a fixative, processed and infiltrated with paraffin wax, placed onto a slide(s), and stained before being reviewed and evaluated by a technical supervisor.

The CLIA State Operations Manual (SOM), Appendix C (''Interpretive Guidelines'') [279] for 42 CFR 493.1489(b)(7) state that gross examinations may be performed by individuals qualified under § 493.1489 as delegated by the technical supervisor. The technical supervisor is not required to provide on-site supervision, but is responsible for the review, accuracy, and confirmation of the macroscopic gross examination in the patient report. The documentation of the review of the results of the macroscopic gross examination by the technical supervisor must be included in the signed microscopic examination report, as

[278] See definition of ''laboratory'', *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.2*.

[279] CLIA Interpretive Guidelines: *https://www.cms.gov/regulations-and-guidance/legislation/clia/interpretive_guidelines_for_laboratories*.

required at § 493.1273(d). The CLIA regulations do not cover the acceptable timeframe in which the review of the gross tissue examination must be completed. The discussion surrounding the review of the gross tissue examination includes CLIA's oversight at this phase of the histopathology testing process. CLIA supports an acceptable timeframe to permit a pathologist to review the tissue specimen prepared during the gross examination by a qualified technical supervisor. This review can be delegated by the technical supervisor to a qualified individual. Gross examination is a critical part of the tissue analysis process to ensure subsequent pathology tests are accurate and reliable. The review of the gross tissue is important to protect the patient's specimen identification during the testing process.

b. Cytology

(1) CLIA Statute and Regulations

CLIA revised section 353 of the Public Health Service Act (42 U.S.C 263a) to authorize the regulation of all clinical laboratories. Section 353(4)(B)(vi) of the Public Health Service Act requires that all cytological screening be done on the premises of a laboratory that is certified under this section.

The CLIA regulations for cytology state that cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology at § 493.1274(a).

(2) Clinical Laboratory Improvement Amendments (CLIA) Guidance for Temporary Testing Sites Under the Multiple Site Exception,[280] CMS Policy Memo (QSO–22–13–CLIA)

The intent of the CLIA program is to ensure that test results provided to individuals and their healthcare providers are accurate, timely, and reliable. During the COVID–19 public health emergency (PHE), we issued memo QSO–22–13–CLIA that informed interested parties that we exercised enforcement discretion to allow pathologists the ability to examine histopathology and cytology slides/images remotely, under the following conditions:

- The primary laboratory's CLIA certificate must include the specialty of pathology with the subspecialties of histopathology and cytology, as appropriate.
- The remote location complies with other applicable Federal laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- The primary laboratory's written procedure manuals for tests, assays, and examinations are available to the pathologists at the remote location.
- Retention time for histopathology slides (10 years), specimen blocks (2 years), preserved tissue remnants (until a diagnosis was made), and cytology slides (5 years) were maintained.
- The use of equipment, supplies and reagents, and similar items needed at the remote location are not allowed to be permanently stored on site.

Under the memorandum, QSO–22–13–CLIA, the remote location could allow pathologists the opportunity to examine histopathology and cytology slides for specified intervals of time to include a PHE, medical condition, or a situation where a pathologist has to examine slides away from the primary location.

Pathologists that currently hold a CLIA certificate are exempt from this enforcement discretion. The pathology community has expressed their desire to make this enforcement discretion a permanent provision after the end of the PHE for COVID–19.

c. Clinical Cytogenetics

We require any testing facility that meets the CLIA regulatory definition of a ''laboratory'' (per § 493.2, *Definitions*[281]) to have a CLIA certificate. A laboratory may choose to outsource a test or a portion of their test procedure because it lacks the equipment, personnel with the expertise in the subject, or is considered more cost-efficient. The CLIA regulations at § 493.1242(c) require the laboratory to only refer a test (for example, reflex, confirmatory, or distributive testing) to another laboratory that is CLIA certified or a laboratory meeting equivalent requirements as determined by CMS. Therefore, each laboratory or testing facility that performs clinical testing must have its own CLIA certificate and comply with the regulations for the complexity of the testing it performs.

Clinical cytogenetics testing is generally categorized as a CLIA high complexity test. A cytogenetics test may be conducted at one facility, or involve a testing workflow model in which one facility performs the analytical bench testing activities (for example, sample processing, extraction, chemical reaction, slide preparation, imaging) and another facility conducts the non-bench testing activities (for example, review of images, analysis, interpretation or reporting of the results). When any part of a test is performed by more than one facility, this testing model is considered distributive testing. CLIA defines distributive testing under § 493.2, *Definitions,* as ''laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.'' Therefore, any facility performing clinical cytogenetics testing activities must be CLIA certified and meet high complexity testing requirements.

During the PHE for COVID–19, we exercised enforcement discretion regarding clinical cytogenetics distributive testing models. Under the enforcement discretion, we allowed clinical cytogenetics personnel the opportunity to examine clinical cytogenetics digital images (that is, non-bench testing activities) at a remote testing location without obtaining a separate CLIA certificate for the remote site under certain conditions. Some interested parties have requested we make this enforcement discretion permanent. Changes to the current CLIA regulations would be necessary to allow the examination of clinical cytogenetics images at a different, remote location from the primary CLIA-certified site without a separate CLIA certificate. Please note that a remote location not associated with or covered by a primary CLIA-certified laboratory would be required to obtain its own CLIA certificate. The primary site laboratory director would be responsible for the overall operation and administration of the laboratory including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately, and proficiently; for assuring compliance with applicable regulations in their primary laboratory; and for the supervision of the personnel reviewing digital laboratory data, digital results, and digital images remotely.

2. Solicitation of Public Comments

We are soliciting public input and comment on the following areas of CLIA: Histopathology; Cytology; and Clinical cytogenetics. The topics listed in this RFI are areas that CMS, CDC,

[280] QSO–22–13–CLIA: *https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-guidance-temporary-testing-sites-under-multiple-site.*

[281] See definition of ''laboratory'', *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.2.*

interested parties, and SA surveyors have identified that may potentially be used by CMS for future rulemaking.

a. Histopathology

We are seeking public comments on the following:

- Whether, and how, CLIA should provide oversight of histopathology preparation and processing of tissue samples for slide staining, specifically related to guidance for routine histopathology slide staining and complex IHC staining.
- What criteria (for example, training programs, on-the-job training, experience, or academic degree) would interested parties recommend for personnel performing high complexity automated IHC staining?
- How does the categorization of automated staining systems impact personnel who are currently performing this task but do not meet the qualifications for performing high complexity testing?
- What is an acceptable timeframe between the review of the macroscopic gross tissue examination, and the review and confirmation of these tissue findings by a pathologist prior to the microscopic review of slides to protect the integrity of the macroscopic tissue?
- What education and experience or training requirements should be required for individuals to qualify as a general supervisor (GS) for histopathology? If qualified, what is an acceptable timeframe for the GS to review and evaluate gross examinations under the specialty of histopathology?
- What education and professional experience, or training requirements should be required for individuals performing gross tissue examination that have an associate degree from a histotechnician program or a PA who has training from an accredited program and is certified as a PA?

b. Histopathology and Cytology Testing at Remote Locations

We are seeking public comments on the following:

- How should ''remote testing location'' be defined?
- How should the CLIA regulations be revised to allow pathologists to examine histopathology and cytology slides/images at a remote testing location?
- What conditions (including, location(s)) should apply for a pathologist to examine histopathology or cytology slides/images remotely without obtaining a separate CLIA certification?
- Under what conditions should a primary location cease permitting testing at the remote location?
- How should the remote location be included on the final patient report?
- How should CMS, SAs, or Accreditation Organizations perform onsite surveys at remote locations?

c. Clinical Cytogenetics

We are seeking public comments on the following:

- Under what circumstances should CLIA allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification?
- Under what circumstances would the examination of clinical cytogenetics images be unacceptable for the remote location scenario?
- What clinical cytogenetics testing processes should the primary laboratory have in place to ensure the remote site complies with the CLIA requirements?
- What ''conditions'' or ''criteria'' would be necessary for the remote location to ensure quality testing for the examination of clinical cytogenetics images?

Q. Changes to the Basic Health Program Regulations

Section 1331 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act or ACA), provides States with the option to operate a Basic Health Program (BHP). In the States that elect to operate a BHP, the State's BHP makes affordable health benefits coverage available for lawfully present individuals under age 65 with household incomes between 133 and 200 percent of the Federal poverty level (or in the case of a lawfully present non-citizen, ineligible for Medicaid or the Children's Health Insurance Program (CHIP) due to immigration status, whose household income is between zero and 200 percent of the FPL) who are not eligible for Medicaid, CHIP, or other minimum essential coverage. As of the date of this proposed rule, only New York and Minnesota have implemented a BHP.

Federal funding for BHP is based on 95 percent of the value of the premium tax credits (PTC) and cost sharing reduction (CSR) subsidies that BHP enrollees would have received had they instead enrolled in Qualified Health Plans (QHPs) through the Exchange in accordance with section 1331(d)(3)(A)(i) of the ACA. These funds are paid to trusts established by the States and dedicated to the BHP, and the States then administer the payments to BHP standard health plans within the BHP. Under section 1331(d)(2) of the ACA, Federal funding for the BHP can only be used to reduce the premiums and cost-sharing of, or to provide additional benefits for, eligible individuals enrolled in standard health plans within the State.

1. Allowing States To Suspend a BHP

Current regulations require States to operate a BHP under a certified Blueprint approved by CMS, and to operate the BHP as long as their approved certified Blueprint is in place. Under 42 CFR 600.140, a State may terminate its BHP, which requires that the BHP trust fund balance must be refunded to the Federal government. A State has inquired about whether it could ''suspend'' its program for a portion of time, so that it could shift BHP enrollees to other coverage with comparable benefits and cost sharing, while maintaining its BHP trust fund, which it could use if the State were to resume the BHP.

We see the value in allowing a State currently operating a BHP to experiment with other ways of providing coverage that may increase the number of people covered while not increasing Federal costs. We propose to give a State the option of temporarily ''suspending'' its BHP program, while retaining accrued funds in the BHP trust fund for a limited period of time. Should the State decide to resume operating its BHP, the suspension would allow the State to leverage accrued funds and avoid the processes of terminating the program and refunding trust funds, and then later having to submit a new BHP application for approval. For that reason, under the authority of section 1331(c)(4) of the ACA, which requires coordination with other State health programs, we are proposing to amend § 600.140 to add an option at paragraph (b) for a State to suspend its BHP.

We propose at § 600.140(b)(1) that States wishing to suspend their BHP must submit an application to HHS. Under proposed § 600.140(b)(1), States could also seek approval to extend a BHP suspension previously approved by HHS. In § 600.140(b)(1)(vi), we propose that the application must be submitted at least 9 months in advance of the proposed effective date of the suspension or extension. In § 600.140(c), we propose that the State cannot implement the suspension or extension without prior approval by the Secretary. However, for States seeking to suspend a BHP in the first plan year that begins

following publication of a final rule adopting this proposal, States must submit an application within 30 days of the publication of such a final rule. HHS will approve or deny such application as expeditiously as possible. We propose in § 600.140(b)(2) that a suspension application would need to be approved prior to the effective date of suspension, except in the case of a State seeking to suspend a BHP in the first plan year that begins following publication of a final rule adopting this proposal.

The proposed substantive requirements for the suspension application are described in § 600.140(b)(1)(i) through (v). During the period of suspension, BHP enrollees should receive comparable coverage that is as comprehensive and affordable as, or more comprehensive and affordable than, BHP coverage during the period of suspension. Therefore, in § 600.140(b)(1)(i) through (iii), we propose to require that the suspension and extension application demonstrates that the benefits that will be provided to individuals that meet the BHP eligibility criteria are at least equivalent to the benefits offered in the State's BHP. We propose that the cost sharing and premiums that will be charged to such individuals under the new coverage option do not exceed the amounts charged under the BHP to reduce the risk that these individuals are harmed by the transition to other coverage.

We propose at § 600.140(b)(1)(i) to require that benefits provided under the new coverage option must be at least equal to the BHP benefits in the certified Blueprint in effect on the effective day of suspension. This is the same standard that is used in the Medicaid regulations at § 440.330 to determine if a State's alternative benefit package is equivalent to the benchmark benefit package. Additionally, it is similar to the standard that is used by CHIP at § 457.420 to determine if a State's CHIP benefit package is equivalent to the benchmark benefit package, although the CHIP standard allows for some variation if the State is adding additional benefits as required by Title XXI. We note that it would be acceptable to provide additional benefits under the new coverage option, such that individuals receive more or greater benefits under the new coverage option. We considered whether there should be a look back period, such that benefits under the new coverage option would be compared to the BHP benefits provided under the certified Blueprint in effect for a period of time prior to the effective date of the suspension and seek comments on this alternative approach.

In order to determine that the cost sharing required of individuals under the new coverage option does not exceed the BHP cost sharing levels, we propose at § 600.140(b)(1)(ii) to require that the actuarial value of the new coverage option must meet or exceed the actuarial value of the BHP standard health plans in effect immediately prior to the suspension period. This may result in cost sharing for individual benefits differing between the BHP and the new coverage program, provided the actuarial value of the new coverage options meets or exceeds the actuarial value of the BHP standard health plans. If there are multiple health plans being offered under the new coverage option and/or multiple standard health plans in effect in the State, we propose that the median actuarial value of the health plans offered under the new coverage option must meet or exceed the median actuarial value of the BHP standard health plans. We considered whether to require that cost sharing under the new coverage option instead meet the cost sharing requirements under current regulations at § 600.520(c) and seek comment on whether this alternative approach should be adopted in the final rule.

Similarly, we propose at § 600.140(b)(1)(iii) to require that the premiums charged to individuals under the new coverage option must be comparable to BHP standard health plan premiums in effect immediately prior to the suspension period, beyond reasonable increases due to inflation as measured by the Consumer Price Index (CPI). We considered alternative methods for measuring equivalency in premiums. First, we considered whether to require that premiums under the new coverage option instead meet the premium requirements under § 600.505(a). Second, we considered whether premiums charged to individuals under the new coverage option should instead not exceed the premiums in effect on December 31, 2020, as these premiums levels do not account for any additional premium tax credit subsidies offered under the American Rescue Plan Act or the Inflation Reduction Act. Third, we considered whether premium and cost sharing levels, considered together, under the new coverage option would be considered sufficient, if those levels meet the requirements under a section 1115 demonstration or section 1332 waiver. We also seek comment on whether these alternative approaches should be adopted in the final rule.

We also considered alternatives to the timing of the comparison of benefits and cost sharing in BHP to the new coverage option. Specifically, we considered whether benefits and cost sharing under the new coverage option should be compared to the benefits and cost sharing under the BHP on the date the suspension application is submitted to HHS, or some other date. We also seek comment on the potential adoption of these alternatives in the final rule.

Finally, we believe that the suspension period should not result in individuals losing coverage, solely due to a change in eligibility criteria for the program. Therefore, we are proposing in § 600.140(b)(1)(iv) that a state must demonstrate in its application that the eligibility criteria for coverage during the suspension is not more restrictive than the criteria described in § 600.305.

We believe that the suspension period should be long enough to allow the State to evaluate the alternative coverage provided to BHP eligible individuals, but should not be indefinite. Therefore, we are proposing in § 600.140(b)(1)(v) that a State could request a suspension of up to 5 years in an initial suspension application, after which a State could request an extension of up to 5 additional years. Additional extension periods would not be allowed. When the suspension period, including any extension period, ends, we propose that the State would need to transition the BHP eligible population back to the BHP, or terminate the BHP. We propose at § 600.140(b)(7) that at least 9 months before the end of the suspension period, a State must submit a transition plan to HHS that explains how the State will reinstate its BHP, or terminate the program under § 600.140(a) of the current regulations. The state must also notify the public of this change. Under proposed § 600.140(b)(7), a State also could elect to end a BHP suspension before the end of the initial or extended suspension period by following the same process.

We chose 5 years for the initial approval period because this aligns with the duration of initial waivers and demonstration projects approved under section 1332 of the ACA and section 1115 of the Act. We believe these are the most likely authorities under which States could seek to provide alternative coverage to BHP enrollees. Similarly, we chose 5 years for the extension period because it aligns with the duration of typical extensions or amendment periods under section 1332 waiver and section 1115 demonstration projects. We considered a shorter extension period of 2 or 3 years, and allowing multiple

extension periods given both section 1332 waiver and 1115 demonstrations can be extended. We seek comment on these alternatives.

Under proposed § 600.140(b)(1)(vii), States requesting an extension of a previously-approved BHP suspension also would need to provide an evaluation of the alternative coverage in its application. In the case of alternative coverage provided through a section 1115 demonstration project or section 1332 waiver, the evaluation and application required for such demonstration projects and waivers would satisfy this requirement.

If individuals and/or standard health plans will experience a change in the terms of the coverage, including receiving additional benefits or being charged different cost sharing amounts, in § 600.140(b)(3), we propose to require that the state provide notice to them at least 90 days prior to the effective date of the suspension. The notices would need to include information regarding the State's assessment of their eligibility for all other insurance affordability programs in the State, and meet the accessibility and readability standards at 45 CFR 155.230(b).

In order to calculate a State's BHP payments, the State provides CMS an estimate of the number of BHP enrollees it projects will enroll in the upcoming BHP program quarter each quarter of program operations. We use those estimates to calculate the prospective payment, which is deposited in the State's BHP trust fund. Once the State provides us with actual enrollment data for those periods, the actual enrollment data is used to calculate the final BHP payment amount and make any necessary reconciliation adjustments to the prior quarters' prospective payment amounts due to differences between projected and actual enrollment.

We believe that having an accurate accounting of the balance of the State's trust fund is critical for any State suspending its BHP. Therefore, we propose to require in § 600.140(b)(4) that States that suspend their BHP must submit the data necessary to complete the BHP payment reconciliation process within 12 months of the effective date of the suspension. We believe that 12 months is a reasonable amount of time for a State to submit the actual enrollment data for the periods it was operating a BHP.

One reason it is important for a State to complete the BHP payment reconciliation process is to establish a baseline balance for calculating interest. Currently, States' BHP trust funds can accrue interest, and this interest is retained in the BHP trust fund. However, we believe that interest accrued on the BHP trust fund during any suspension must be remitted to HHS. Since the State is not operating a BHP during the suspension period, suspension should not generate additional funds for the State. We propose in § 600.140(b)(6) that while the State is not providing BHP coverage, any accrued interest on the trust fund must be remitted to HHS on an annual basis in the form and manner set out by HHS.

States currently submit the balance of their trust fund and any interest accrued through the BHP annual report described in § 600.170. We proposed revisions to §§ 600.140(b) and 600.170(a) to require States that suspend their BHP continue to submit an annual report in order to document the interest earned and to provide assurance that the coverage provided to BHP-eligible individuals meets the standards discussed above. We propose in § 600.140(b)(5) to require States that suspend their BHP continue to submit an annual report during the suspension period. We proposed amendments to § 600.170(a), which describes the requirements for the annual reports, to describe the standards that will apply to States that have suspended their BHP. Specifically, we propose to redesignate the introductory language in paragraph (a) as paragraph (a)(1), to redesignate paragraphs (a)(1) through (a)(4) as paragraphs (a)(1)(i) through (a)(1)(iv), and to add a new paragraph § 600.170(a)(2) to require that States that have suspended their BHP under § 600.140(b) must submit an annual report that includes (1) the balance of the BHP trust fund and any interest accrued on that balance; (2) an assurance that the coverage provided to individuals who would be eligible for a BHP under § 600.305 continues to meet the standards described in § 600.140(b)(1)(i) through (iii); and (3) any additional information specified by the Secretary at least 120 days prior to the date that the annual report is due.

If a State does not meet the proposed requirements (that is, completing the financial reconciliation process, remitting interest on the trust fund, and submitting the required information in its annual report), we propose in § 600.140(d) that the Secretary can withdraw approval of the suspension. Specifically, we propose that the Secretary can withdraw approval of the suspension if the State ends implementation of the alternative coverage program for any reason, or if the State fails to continue to meet the coverage and cost sharing requirements of the alternative coverage program. If the State seeks an amendment to the alternative coverage program, the State must inform CMS of this proposed change so that CMS may evaluate if the coverage is sufficient. In addition, we propose at paragraph (d) that we could also withdraw approval if we have significant evidence of harm, financial malfeasance, fraud, waste, or abuse consistent with § 600.142. In § 600.140(d)(1) through (4), we propose a process for withdrawing approval, which mirrors the process for withdrawing certification of a BHP Blueprint in § 600.142. Specifically, we propose that the Secretary will withdraw approval only after providing the State with notice of the findings upon which the Secretary is basing the withdrawal, a reasonable period for the State to address the finding, and an opportunity for a hearing before issuing a final finding. We propose that the Secretary shall make every reasonable effort to resolve proposed findings without withdrawing approval of the suspension plan and in the event of a decision to withdraw approval, will accept a request from the State for reconsideration. The effective date of an HHS determination withdrawing approval of the suspension plan would not be earlier than 120 days following issuance of a final finding. Within 30 days following a final finding under paragraph (d)(1) of this paragraph, the State shall submit a transition plan to HHS.

During the transition period from the BHP to other coverage the state may not use funds from the BHP trust fund toward the unwinding of the BHP program and transition to the new coverage program. Under section 1331(d)(2) of the ACA and current regulations at § 600.705(c), Federal funding for BHP can only be used to reduce the premiums and cost-sharing, or to provide additional benefits, for BHP-eligible individuals enrolled in standard health plans within the State. Therefore, Federal funding is not available for administrative expenses associated with transitioning BHP enrollees to a new coverage program or for costs associated with providing new coverage after the transition has occurred. States cannot use Federal BHP funding to cover premiums and cost sharing (or additional benefits) for individuals that would otherwise be eligible for BHP funding. We solicit comment on these proposals.

We seek comment on the proposed process for suspending a BHP. Specifically, we seek comment on how far in advance of suspension a state must submit a suspension application to CMS and how far in advance of

suspension CMS must approve or deny the suspension request. We also seek comment on duration of time a state may suspend their BHP, without terminating the program.

2. Submission and Review of BHP Blueprints

As noted above, under current § 600.110, States must submit to the Secretary and receive certification of a BHP Blueprint describing their operational design choices prior to implementation. Under the current § 600.125(a) a State that seeks to make significant changes to its BHP must submit a revised Blueprint to the Secretary for review and certification; however, the current regulation does not specify any timeframes for the submission and review of revised Blueprints. The current § 600.125(a) also describes a limited number of changes under which submission of a revised Blueprint is required. Most notably, the current regulation does not require the submission of a revised Blueprint in response to changes in Federal law or regulations. Additionally, under current § 600.125(a) and (b), any changes made in a revised Blueprint can be implemented prospective from the date of certification; no changes can be implemented until HHS certifies the revised Blueprint.

We believe that additional parameters are necessary in order to ensure effective and efficient operation of the BHPs and HHS review of a revised Blueprint, consistent with section 1331(a)(1) of the ACA. Therefore, we propose changes to § 600.125 to establish timeframes and procedures for the submission and review of BHP Blueprints, similar to the Medicaid and CHIP State plan amendment (SPA) submission and review processes. We note that these proposed timeframes only apply to the submission and review of revised Blueprints; we are not proposing changes to the timeframes for the submission and review of an initial Blueprint, set forth in current regulations at § 600.120, in the event additional States seek to establish BHPs.

Additionally, we believe States need flexibility to receive approval of a retroactive effective date for changes to their BHP Blueprint, similar to flexibilities allowed under regulations at §§ 430.20(b) and 457.60 for the submission of Medicaid and CHIP SPAs. We note, however, that in the event that a State implements a change to its BHP Blueprint that is ultimately disapproved by HHS, the State could be required to implement a corrective action plan under § 600.715.

Specifically, under existing regulations at § 600.125(a), States must submit a revised Blueprint whenever they seek to make significant change(s) that alter program operations the BHP benefit package, enrollment, disenrollment and verification policies described in its certified BHP Blueprint. Under the proposed revisions to § 600.125(a), we would broaden the circumstances requiring submission of a revised Blueprint to include States' significant changes that alter any core program operations under § 600.145(f). States also would be required to submit a revised Blueprint to HHS whenever necessary to reflect changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in their certified Blueprint. States would continue to be required to submit a revised Blueprint to make changes to the BHP benefit package or to enrollment, disenrollment, and verification policies described in the certified Blueprint, as currently required under § 600.125(a).

At § 600.125, we also propose to redesignate paragraph (b) as paragraph (d) and to add new paragraph (b) to provide that the effective date of a revised Blueprint may be as early as, but not earlier than, the first day of the quarter in which an approvable revision is submitted to HHS. This policy mirrors the standards for submission of a Medicaid SPA at § 430.20(b). The current regulations do not specify as to when revision is considered received. We believe that it is reasonable to consider a revised Blueprint to be received when HHS receives an electronic copy of a cover letter signed by the Governor or Governor's designee and a copy of the currently approved Blueprint with proposed changes indicated in track changes. In the event a State is unable to submit a revised Blueprint electronically, due to a disaster or other event outside of the State's control, CMS may consider other modes of submission on a case-by-case basis. Under current regulations at § 600.125(b), redesignated at § 600.125(d) in this proposed rule, the State is responsible for continuing to operate under the terms of the existing certified Blueprint until the State adopts a revised Blueprint, the State terminates or suspends the BHP, or the Secretary withdraws certification for the BHP.

We are also proposing to redesignate paragraph (c) as paragraph (g) and to add a new paragraph (c) to create clear timelines for HHS's review, approval, and disapproval of revised Blueprints similar to the timelines currently applicable to CHIP SPAs under § 457.150. Under proposed § 600.125(c)(1), a revised Blueprint will be deemed approved unless HHS, within 90 days after receipt of the revised Blueprint, sends the State written notice of disapproval or written notice of additional information HHS needs in order to make a final determination. If HHS requests additional information, the 90-day review period will be stopped and will resume the day after HHS receives all of the requested additional information from the State. Under proposed paragraph (c)(2), if 90 days from the date a Blueprint revision is received does not fall on a business day, the 90-day review period will end on the next business day. Under proposed paragraph (c)(3), HHS may send written requests for additional information as many times as needed to obtain all information necessary to certify the revised Blueprint. This mirrors the process used by CHIP, of having one 90-day review period that can start and stop multiple times with a request for additional information and response. It differs from Medicaid, which has a 90-day review period that can be stopped once by a request for additional information, followed by a second 90-day review period when the state responds. At paragraph (c), we propose that HHS may disapprove a Blueprint amendment if the Secretary determines that the Blueprint revision is not consistent with section 1331 of the ACA or the regulations set forth in this part at any time during the review process, including when the 90-day review clock is stopped due to a request for additional information.

Once a Blueprint is approved, current paragraph (b) specifies that the State is responsible for continuing to operate under the terms of the existing certified Blueprint until and unless a revised Blueprint that seeks to make significant change(s) is certified, except during a public health emergency, as described in paragraph (c). We propose to revise paragraph (b), redesignated as paragraph (d) in this proposed rulemaking, to provide that the State must continue to operate under the terms of an existing certified Blueprint until the State adopts a revised Blueprint, terminates the BHP following the procedures described in § 600.140(a), suspends the BHP following the procedures described in § 600.140(b), or the Secretary withdraws certification of the BHP under § 600.142.

Finally, we propose to apply some of the existing parameters for initial Blueprint submissions to Blueprint revisions. In paragraph (e), we propose that a State may withdraw the proposed revised Blueprint during HHS review if the State has not yet implemented the

proposed changes and provides written notice to HHS. This proposal mirrors current § 600.130 for initial BHP Blueprints. In paragraph (f), we propose that HHS will accept a State's request for reconsideration of a decision not to certify a revised Blueprint and provide an impartial review against standards for certification if requested. This proposal mirrors current § 600.135(c) for initial BHP Blueprints.

Under current § 600.135, HHS must act on all initial BHP Blueprint certification and revision requests in a timely matter. Because we are proposing to specify timeframes for the submission and review of revised BHP Blueprints under § 600.125, we propose to revise § 600.135 to apply only to the submission of initial BHP Blueprints. Specifically, we propose to revise the title to clearly state that this section is applicable to only initial Blueprints and to remove the reference to BHP Blueprint revisions in paragraph (a).

3. BHP Notices

Under current § 600.330, States must provide written notice to beneficiaries conveying final determination of eligibility or ineligibility. The regulation does not require States to provide those notices in a manner that is accessible to individuals with disabilities or limited English proficiency (LEP). Although HHS Office for Civil Rights regulations at 45 CFR 92.101, which apply to programs such as Medicaid, CHIP and BHP, require States to take reasonable steps to provide meaningful access for individuals with LEP and to ensure effective communication with individuals with disabilities, we believe it is important for these obligations to also be described clearly in the BHP regulations. Therefore, we are proposing to add paragraph (f) to § 600.330 to require that BHP eligibility notices be written in plain language and be provided in a manner which ensures that eligible individuals with LEP are provided with meaningful language access and individuals with disabilities are provided with effective communication.

4. BHP Appeals

Under current § 600.335(b), individuals must be given the opportunity to appeal BHP eligibility determinations through the appeals rules of the State's Medicaid program or the Exchange, as indicated in the State's Blueprint. Current BHP and Exchange regulations do not provide for appeals of health services matters. We believe all BHP enrollees should be afforded the opportunity to appeal not only eligibility determinations but also decisions about health services matters. The Exchange rules do not include an opportunity to appeal a health services matter, as such appeals are typically handled by State Departments of Insurance, as opposed to by the Exchange itself. Therefore, we propose in paragraph (b) to remove the option for States to conduct their BHP appeals process according to Exchange rules. In paragraph (b)(2), we propose to require States to provide individuals an opportunity to appeal a delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of service, after individuals exhaust appeals or grievances through the BHP standard health plans.

Because current BHP regulations do not include provisions related to the appeal of health services matters, these appeals are not currently included in the list of core operations of a BHP in § 600.145. We believe that appeals of health services matter, like appeals of eligibility determinations, are a core function of a BHP. Therefore, in proposed § 600.145(f)(2), we include appeals of health services matters as specified in § 600.335 as a core operation of a BHP.

R. Updates to the Definitions of Certified Electronic Health Record Technology

1. Background

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted February 17, 2009) (ARRA), authorized incentive payments to eligible professionals, eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). In 2010, the Office of the National Coordinator for Health Information Technology (ONC) launched the Health IT Certification Program (ONC Health IT Certification Program) to provide for the certification of health information technology (IT), including EHRs. Requirements for certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary pursuant to section 3004 of the Public Health Service Act. The ONC Health IT Certification Program supports the use of certified health IT under the programs that we administer, including, but not limited to, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), the Shared Savings Program, and the Quality Payment Program, which includes the MIPS Promoting Interoperability performance category and the Advanced Alternative Payment Models (Advanced APMs). While these programs continue to require the use of CEHRT, the use of certified health IT has expanded to other government and non-government programs.

For CY 2019 and subsequent years, the definitions of CEHRT for the Promoting Interoperability Programs at 42 CFR 495.4, the Quality Payment Program at 42 CFR 414.1305, and the Shared Savings Program at 42 CFR 425.20 require the use of EHR technology that meets the 2015 Edition Base EHR definition at 45 CFR 170.102 and is certified to 2015 Edition health IT certification criteria under the ONC Health IT Certification Program. In addition, the CEHRT definitions in our regulations for these programs require technology to be certified to certain specific 2015 Edition health IT certification criteria, as specified in each of the definitions, including criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program, and criteria necessary to report on applicable objectives and measures specified under the MIPS Promoting Interoperability performance category under the Quality Payment Program. Prior Editions of health IT certification criteria were associated with ''stages'' of the EHR Incentive Programs (now the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category), which linked new and updated functionality in certified health IT to significant revisions to the objectives and measures in the programs.

In the CY 2021 PFS final rule (85 FR 84815 through 84825), we finalized that the technology used by health care providers to satisfy the definitions of CEHRT at 42 CFR 495.4 and 42 CFR 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria (2015 Edition Cures Update), as finalized in the ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (Cures Act) final rule (85 FR 25642). We further finalized aligning the transition period during which health care providers participating in the Medicare Promoting Interoperability Program, the MIPS Promoting Interoperability performance category, and the Advanced Alternative Payment Models (Advanced APMs) may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December

31, 2022 date established in the ONC interim final rule, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency (85 FR 70064), for health IT developers to make updated certified health IT available (85 FR 84815 through 84825). After this date, health care providers were required to use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period in CY 2023.

In the ONC ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' proposed rule (88 FR 23746 through 23917) (hereafter referred to as ''ONC HTI–1 proposed rule''), which appeared in the **Federal Register** on April 18, 2023, ONC has proposed to discontinue the year themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules (88 FR 23758). In the proposed rule, ONC noted public comments stating that the continued use and reference to the 2015 Edition inaccurately implies an age and outdatedness to the certification criteria ONC has adopted. Given these concerns, ONC stated that it believes there should be a single set of certification criteria, which will be updated in an incremental fashion in closer alignment to standards development cycles and regular health IT development timelines (88 FR 23750).

ONC further stated its belief that maintaining a single set of ''ONC Certification Criteria for Health IT'' would create more stability for the ONC Health IT Certification Program and for Federal partners who reference the ONC Health IT Certification Program, as well as make it easier for developers of certified health IT to maintain their product certificates over time (88 FR 23759). ONC stated this proposal to remove ''editions'' from the ONC Health IT Certification Program would also help users of certified health IT identify which certification criteria are necessary for their participation in programs, such as the Medicare Promoting Interoperability Program, the Shared Savings Program, and the Quality Payment Program's MIPS Promoting Interoperability performance category and Advanced APMs (88 FR 23760). For example, users would only need to know that their Health IT Module is certified to 45 CFR 170.315(b)(3), electronic prescribing, for successful participation in the MIPS Promoting Interoperability performance category related to electronic prescribing, as compared to the current state, where they must also know if the Health IT Module supports electronic prescribing as part of the 2014 Edition Certification Criteria or the 2015 Edition Certification Criteria, or 2015 Edition Cures Update Certification Criteria. To implement this approach, ONC has proposed to rename all criteria within the ONC Health IT Certification Program simply as ''ONC Certification Criteria for Health IT,'' proposing associated changes to the regulations at 45 CFR part 170 (88 FR 23759).

Similar to ONC's proposal to move away from ''editions'' and toward incremental changes to its certification criteria, we also have focused on implementing incremental changes to individual measures under, but not limited to, the Medicare Promoting Interoperability Program, the Shared Savings Program, and the Quality Payment Program, which includes the MIPS Promoting Interoperability performance category and the Advanced APMs in recent years. We expect to continue to prioritize incremental changes in future years to reduce burden on participants in these programs (including eligible hospitals and CAHs and MIPS eligible clinicians), and build on the established base of available certified health IT capabilities. We believe our approach is consistent with the strategy discussed in the ONC HTI–1 proposed rule, in which ONC proposes to pursue a framework for the ONC Health IT Certification Program that focuses on incremental updates to a single set of certification criteria.

2. Updates to the Definition of Certified Electronic Health Record Technology in the Medicare Promoting Interoperability Program and the Quality Payment Program

a. Background and Previously Finalized Certification Requirements

In consideration of the updates made to the 2015 Edition certification criteria as described in the CY 2021 PFS final rule (85 FR 84815 through 84828), we finalized that health care providers participating in the Medicare Promoting Interoperability Program and eligible clinicians participating in the Quality Payment Program must use certified health IT that satisfies the definitions of CEHRT at 42 CFR 495.4 and 42 CFR 414.1305, respectively, and is certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria, as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We explained this included technology used to meet the 2015 Edition Base EHR definition at 45 CFR 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and technology certified to the criteria necessary to report on applicable objectives and measures. In this proposed rule, we are proposing revisions to the CEHRT definitions in the Medicare Promoting Interoperability Program and the Quality Payment Program (on which the Shared Savings Program's definition of CEHRT at § 425.20 also relies) to support the proposed transition from the historical state of year themed ''editions'' to the ''edition-less state'' in the ONC HTI–1 proposed rule.

We included Table IX.H.–04 in the Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2024 Rates proposed rule (88 FR 27170), which includes some, but not all, certification criteria for the Medicare Promoting Interoperability Program's measures and eCQMs for eligible hospitals and CAHs, and Table 48 in section IV.A.4.f.(4)(e)(iv) of this proposed rule, which includes some, but not all, certification criteria for measures under the MIPS Promoting Interoperability performance category. These tables are only applicable for the measures under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, and do not include all of the updated certification criteria included in the CEHRT definition as discussed in the CY 2021 PFS proposed rule (85 FR 50265 through 50270). For further discussion on the complete list of changes to the certification criteria under the CEHRT definition, we refer readers to the ONC 21st Century Cures Act final rule (85 FR 25667), the CY 2021 PFS proposed rule (85 FR 50265), and the CY 2021 PFS final rule (85 FR 84818 through 84825).

b. Proposed Revisions to Certified Electronic Health Record Technology Definitions in Regulatory Text

We are proposing to revise the definitions of CEHRT in 42 CFR 495.4 and 42 CFR 414.1305 for the Medicare Promoting Interoperability Program and for the Quality Payment Program so these definitions would be consistent with the ''edition-less'' approach to health IT certification as proposed in the ONC HT–1 proposed rule, should the ONC proposal be finalized. First, with respect to references to the ''2015

Edition Base EHR definition'' defined at 45 CFR 170.102, we are proposing to add a reference to the revised name ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if finalized, it is applicable for the CEHRT definitions going forward (88 FR 23759). Next, we are proposing to replace our references to ''2015 Edition health IT certification criteria,'' with ''ONC health IT certification criteria'' and to add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. By removing the reference to the ''2015 Edition,'' and pointing to the regulations at 45 CFR 170.315, we believe this proposal, if finalized, will ensure the CEHRT definitions do not need to be updated to reflect modified terminology unless ONC changes the location of these certification criteria.

While these proposed revisions would allow us to maintain more permanent cross-references to ONC's regulations and terminology, we recognize that ONC has historically updated, and will likely in the future continue to update over time, the underlying certification criteria contained in 45 CFR 170.315.

Previously under the year-themed ''editions'' construct, we periodically revised the language in our regulatory CEHRT definitions to refer to a new Edition in order to incorporate ONC's updates to health IT certification criteria. Then, in the CY 2021 PFS final rule (85 FR 84818 through 84825), to incorporate ONC's updates to certification criteria in its 2015 Edition Cures Update, which ONC finalized under the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961), we did not revise the language of the CEHRT definitions for the Medicare Promoting Interoperability Program and the Quality Payment Program. Instead, we finalized that technology used to satisfy the CEHRT definitions must be certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria as finalized in the ONC 21st Century Cures Act final rule.

Consistent with ONC's proposal to move away from year-themed ''editions,'' and in order to further simplify our regulatory approach, we are proposing revisions to our definitions of CEHRT to ensure we would not necessarily be required to update our regulatory text each time ONC proposed or finalized any updates to its definition of Base EHR or certification criteria.

This proposal would establish that any certification criteria adopted or updated in 45 CFR 170.315 would be applicable for the CEHRT definitions in our programs' regulations at 42 CFR 495.4 and 42 CFR 414.1305, if ONC's applicable regulations are referenced directly in our CEHRT definitions. If finalized, this proposal would allow the CEHRT definitions in our regulations to automatically incorporate ONC's updates to relevant certification criteria without pursuing additional rulemaking.

It is important to note that this proposal, if finalized, would not mean that any update to a certification criterion finalized by ONC would necessarily be immediately required for use in CEHRT for our Medicare Promoting Interoperability Program, Quality Payment Program, and Shared Savings Program. We remind readers that ONC sets timelines through their rulemaking for when health IT developers must ensure their health IT products meet ONC's new or updated certification criteria to maintain certification under the ONC Health IT Certification Program, including time for health IT developers to implement these updates for their customers who may participate in programs that require use of CEHRT (88 FR 23761). We also note that CMS will continue to determine when new or revised versions of measures that require the use of certified health IT would be required for participation under the Medicare Promoting Interoperability Program and the Quality Payment Program. In determining requirements for any potential new or revised measures, we will consider factors such as implementation time and provider readiness to determine when we propose requiring participants to complete measures that require the use of certified health IT.

We believe this approach would provide us with more flexibility to finalize updates and is more consistent with the incremental approach to revising measures and technology requirements described above. Moreover, this additional flexibility would allow eligible hospitals, CAHs, and MIPS eligible clinicians to adopt, implement, and use ONC's updated certification criteria for health IT, including EHRs, as it becomes available from their chosen vendor, without the need to wait for us to first amend the regulations at 42 CFR 495.4 and 42 CFR 414.1305 through separate rulemaking.

In summary, we are proposing to revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4, and for the Quality Payment Program at 42 CFR 414.1305. Specifically, we are proposing to add a reference to the revised name of ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if finalized, it is applicable for the CEHRT definitions going forward (88 FR 23759). We are also proposing to replace our references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria'' and add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We also propose to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria in 45 CFR 170.315 ''as adopted and updated by ONC.'' We believe that these revisions to the CEHRT definitions, if finalized, would ensure that updates to the definition at 45 CFR 170.102 and updates to applicable health IT certification criteria in 45 CFR 170.315 would be incorporated into the CEHRT definitions, without additional regulatory action by CMS.

Finally, we note that while this proposal is consistent with the approach in ONC's HTI–1 proposed rule (88 FR 23746 through 23917), we do not believe that ONC must finalize its proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT.

We are inviting public comment on these proposals.

S. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

Medicare coverage for the Annual Wellness Visit (AWV) under Part B is primarily described in statute at section 1861(hhh) of the Act, and in regulation at 42 CFR 410.15. We propose to exercise our authority in section 1861(hhh)(2)(I) of the Act to add other elements to the AWV by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. The proposed new SDOH Risk Assessment would enhance patient-centered care and support effective administration of an AWV. There are no deductible requirements or Part B coinsurance for the AWV. See §§ 410.160(b)(12) and 410.152(l)(13). Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit (see section II.E. of this proposed rule).

1. Background

The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention

plan. The AWV also includes an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months. The goals of AWV are health promotion, disease prevention and detection and include education, counseling, a health risk assessment, referrals for prevention services, and a review of opioid use. Additional information about the AWV is available on the CMS website at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html*.

It is estimated [282] that around 50 percent of an individual's health is directly related to SDOH, which is defined by Healthy People 2030 [283] as, ''The conditions in the environment where people are born, live, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.'' Healthy People 2030 also defines the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context. These parameters include factors like housing, food and nutrition access, and transportation needs. Given the large impact on health these factors have, the health care system broadly has been working to take these factors into account when providing care and rendering services.

Several Federal agencies, including the CDC, AHRQ, ACL, ACF, SAMHSA, HRSA, and ASPE are developing policies and implementation frameworks to better address the impact SDOH has on patients, in support of HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity.[284] At CMS, addressing SDOH is an essential piece of the CMS Framework for Health Equity,[285] and it is tied in heavily with the CMS Strategic Pillar to advance equity. SDOH was also a foundational concept with the CMS Innovation Center Accountable Health Communities (AHC) Model that ended in 2022. Given the importance of and focus surrounding SDOH and enhancing equity, CMS is exploring ways to recognize and quantify practitioner work currently being done in this area, and to provide support to enable practitioners to assess and intervene when SDOH is relevant to the assessment, prevention and treatment plan of a Medicare patient.

CMS tested the AHC Model between 2017 and 2022. One element of the model test was the development and application of the AHC Health-Related Social Needs (HRSN) Screening Tool, which helps providers to identify patients' SDOH related needs, including housing instability, food insecurity, family and community support and mental health. Additional information on the AHC model is available on the CMS website at *(https://innovation.cms.gov/innovation-models/ahcm).*

We have heard from many health care professionals and beneficiary groups that there are barriers to completing the AWV, including, but not limited to, language and communication, differences in cultural perspectives and expectations regarding engagement with the healthcare system. We increasingly understand the importance that SDOH be considered in an assessment of patient histories, patient risk, and in informing medical decision making, prevention, diagnosis, care and treatment.

In February 2018, Health Affairs published an article titled, ''Practices Caring for the Underserved Are Less Likely to Adopt Medicare's Annual Wellness Visit,'' which described findings from a statistical study of Medicare primary care providers and AWV's from 2011 to 2015. The article points out, ''One of our most striking results was that while underserved patients were less likely to receive an annual wellness visit regardless of where they sought care, practices in rural areas and those caring for underserved and sicker populations were less likely to provide such visits to any of their patients—which suggests these practices may face resource constraints or have priorities that compete with adoption of the visit.'' [286]

In August 2022, the Journal of the American Geriatrics Society published an article titled, ''Medicare's annual wellness visit: 10 years of opportunities gained and lost.'' The article expresses the concern, ''currently AWVs are a 'one size fits all','' approach. This uniform approach does not sufficiently take into consideration the medical, psychological, functional, racial, cultural and socio-economic diversity of older adults. Updated AWVs should be tailored to meet the needs and priorities of older adults receiving them.'' It goes on to recommend, ''Medicare AWVs should include screening and counseling for social determinants of health as a means of mitigating the growing disparities in health and longevity for underserved older adults.'' [287]

2. Statutory and Regulatory Authority

Section 4103 of The Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148) expanded Medicare coverage by adding the AWV benefit at section 1861(hhh) of the Act, effective for services furnished on or after January 1, 2011. We subsequently implemented the AWV in CMS regulations at § 410.15. The AWV is a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the AWV differ from comprehensive physical examination protocols with which some providers may be familiar since it is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act. The AWV includes a health risk assessment (HRA) and the AWV takes into account the results of the HRA. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an IPPE or AWV within the past 12 months. Section 1861(hhh)(2) of the Act describes a number of elements included in the AWV and section 1861(hhh)(2)(I) of the Act authorizes the addition of any other element determined appropriate by the Secretary.

We note that § 410.15(a) requires that the first AWV include the following:

- Review (and administration if needed) of a health risk assessment (as defined in § 410.15).
- Establishment of an individual's medical and family history.

[282] *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*

[283] *https://health.gov/healthypeople.*

[284] *https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf.*

[285] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[286] Ganguli I, Souza J, McWilliams JM, Mehrotra A. Practices Caring For The Underserved Are Less Likely To Adopt Medicare's Annual Wellness Visit. Health Aff (Millwood). 2018 Feb;37(2):283–291. doi: 10.1377/hlthaff.2017.1130. PMID: 29401035; PMCID: PMC6080307.

[287] Coll PP, Batsis JA, Friedman SM, Flaherty E. Medicare's annual wellness visit: 10 years of opportunities gained and lost. J Am Geriatr Soc. 2022 Oct;70(10):2786–2792. doi: 10.1111/jgs.18007. Epub 2022 Aug 17. PMID: 35978538.

• Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.

• Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.

• Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.

• Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.

• Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in § 410.15 may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

• Establishment of the following:

++ A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in § 410.15), health status, screening history, and age-appropriate preventive services covered by Medicare.

++ A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE (as described under § 410.16), and a list of treatment options and their associated risks and benefits.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ Any other element determined appropriate through the national coverage determination process.

We note that § 410.15(a) requires that a subsequent AWVs include the following:

• Review (and administration, if needed) of an updated health risk assessment (as defined in § 410.15).

• An update of the individual's medical and family history.

• An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

• Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.

• Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.

• An update to the following:

++ The written screening schedule for the individual as that schedule is defined in paragraph (a) of § 410.15 for the first AWV providing personalized prevention plan services.

++ The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of § 410.15.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ Any other element determined appropriate through the national coverage determination process.

In the CY 2016 PFS final rule (80 FR 70885), we finalized a proposal to include ACP as an optional element (at beneficiary discretion) within the AWV. We stated in the final rule we are adding ACP as a voluntary, separately payable element of the AWV. We are instructing that when ACP is furnished as an optional element of AWV as part of the same visit with the same date of service, CPT codes 99497 and 99498 should be reported and will be payable in full in addition to payment that is made for the AWV under HCPCS code G0438 or G0439, when the parameters for billing those CPT codes are separately met, including requirements for the duration of the ACP services. Under these circumstances, ACP should be reported with modifier -33 and there will be no Part B coinsurance or deductible, consistent with the AWV (80 FR 70958). We also added this policy to the regulatory text at § 410.15(a).

3. Proposal

We propose to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment. We recognize that, for some patients, identification and consideration of SDOH is critical to furnishing a fully informed health assessment and personalized prevention plan in the AWV. We have heard from interested parties that the current elements of the AWV may not directly or adequately identify those SDOH challenges. We propose that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same

date of service as the AWV. We propose that the SDOH Risk Assessment service include the administration of a standardized, evidence-based SDOH risk assessment tool, furnished in a manner that all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We believe that services that are culturally and linguistically appropriate are critical to providing effective, equitable, understandable, and respectful quality care that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs of each patient. We recognize that patients with SDOH risks and challenges may often also experience communication barriers of various kinds when interacting with the health care system. We believe that the SDOH Risk Assessment would only be effective in informing the greater AWV (including the health assessment and personalized prevention plan) when furnished in a manner that is intelligible and appropriate to the individualized characteristics and circumstances of the patient. Additional information on culturally and linguistically appropriate services in healthcare can be found at (*https://thinkculturalhealth.hhs.gov/clas*). We believe the SDOH Risk Assessment Tool would be most effective and actionable when furnished in a setting with staff-assisted supports in place to ensure follow-up for health-related social needs associated to the visit. We also encourage partnerships with community-based organizations such as Area Agencies on Aging to help address identified social needs. We propose that the SDOH Risk Assessment be furnished as part of the same visit and on the same date of service as the AWV, so as to inform the care the patient is receiving during the visit, including taking a medical and social history, applying health assessments and prevention services education and planning. We believe our proposal will directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, in support of the existing AWV. In addition, we hope that our proposal will help spread general awareness among health professionals about the importance of providing cultural and linguistically appropriate services, which in turn will encourage clinicians to adopt language services and technologies to achieve high quality communication between the practitioner and patient. Our goal is the development of a personalized prevention plan that takes SDOH into account and is truly tailored to the individual patient. We invite public comment on our proposal, including whether a SDOH Risk Assessment would ultimately inform and result in the development of steps to address and integrate SDOH in the patient's AWV health assessment and personalized prevention plan.

We recognize that SDOH risk assessments are an emerging and evolving tool in healthcare and so we do not restrict our proposal to a specific list of approved assessments. In selecting an evidence-based tool, we encourage clinicians to explore the many widely adopted and validated tools available, including the CMS Accountable Health Communities [288] tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) tool,[289] and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.[290] We also encourage clinicians, where feasible, to select screening instruments that maximize opportunities to collect and analyze standardized, quantifiable, and actionable data. For instance, clinicians are encouraged to utilize screening instruments where questions and responses are computable and mapped to health IT vocabulary standards (that is, have available LOINC® coding terminology), to ensure that data captured through assessments is interoperable and can be shared, analyzed and evaluated across the care continuum.

Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an E/M visit. See section II.E. for additional information on coding, pricing, and additional conditions of payment for the proposed new SDOH Risk Assessment service. Upon finalization of the CY 2024 PFS, CMS will issue public guidance in the Medicare Learning Network, the Medicare & You Handbook, and more formal, in-depth policy and payment instructions in the Medicare Benefit Policy Manual and the Medicare Claims Processing Manual on the CMS website.

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients by recommending the assessment of SDOH through position or discussion papers,[291] [292] [293] organizational strategic plans,[294] and provider training modules,[295] among others. As described earlier in our proposed rule, we have discussed how the practice of medicine currently includes assessment of health-related social needs or SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally performed by physicians and other health professionals in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. Practitioners are expending resources to obtain information from the patient about health-related social needs, and to formulate diagnosis and treatment plans that take these needs into account as part of a person-centered care plan for the treatment of medical problems. This work currently is reported and paid for, in part, under the PFS under E/M visit codes, and we believe as such, is undervalued and not optimized to allow the health professional and patient to benefit from the full value of a dedicated SDOH assessment and have that assessment immediately inform the health assessment and prevention planning services in the AWV.

We propose that Medicare would pay 100 percent of the fee schedule amount for the SDOH Risk Assessment service (beneficiary cost sharing would not be applicable) when this risk assessment is furnished to a Medicare beneficiary as an optional element within an AWV (as part of the same visit with the same date of service as the AWV). Our proposal is

[288] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[289] *https://www.nachc.org/research-and-data/prapare/.*

[290] CMS–10825.

[291] *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html.*

[292] *https://doi.org/10.7326/M17–2441.*

[293] *https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/.*

[294] *https://www.ama-assn.org/system/files/2021–05/ama-equity-strategic-plan.pdf.*

[295] *https://edhub.ama-assn.org/steps-forward/module/2702762.*

analogous to our current approach to the ACP service, which is an optional service for which beneficiary cost sharing is not applicable when furnished as part of the same visit and on the same date of service as the AWV. Beneficiary cost sharing is not applicable to the AWV and, because the SDOH Risk Assessment would be an optional element within the AWV, there would not be any beneficiary cost sharing for the SDOH Risk Assessment either. See §§ 410.160(b)(12) and 410.152(l)(13). We note that beneficiary cost sharing would apply to the SDOH Risk Assessment if furnished in conjunction with another service (outside of the AWV) that is subject to beneficiary cost sharing. We are proposing that the SDOH Risk Assessment would be optional for both the health professional and the beneficiary to empower clinicians and patients to employ this assessment only when appropriate and desired.

We propose to add regulatory text at § 410.15 that will include the new SDOH Risk Assessment service as an optional element within the AWV, at the discretion of the health professional and beneficiary. Furthermore, we propose to add regulatory text that the SDOH Risk Assessment be standardized, evidence-based, and furnished in a manner that all communication with the patient be appropriate for the beneficiary's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We invite public comment on our proposal.

We have also received feedback from interested parties that the AWV may be more effectively furnished if elements were allowed to be completed over multiple visits and days, or prior to the AWV visit. We invite public comment on this issue for consideration in future rulemaking.

4. Summary

In conclusion, we are proposing to add a new Social Determinants of Health (SDOH) Risk Assessment as an optional element within the AWV. We are also proposing the SDOH Risk Assessment be paid at 100 percent of the fee schedule amount of the risk assessment. We are proposing that the new SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. We believe our proposal will directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, as an additional, optional element in the AWV service.

IV. Updates to the Quality Payment Program

A. CY 2024 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the proposed rule sets forth changes to the Quality Payment Program starting January 1, 2024, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on our measurement efforts and refining how clinicians would be able to participate in a more meaningful way, to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) for the CY 2024 performance period/2026 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a payment incentive program, by which the Medicare program rewards clinicians who provide high-value, high-quality services in a cost-efficient manner. The Quality Payment Program includes two participation tracks for clinicians providing services under the Medicare program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined in 42 CFR at 414.1305) are subject to a MIPS payment adjustment (positive, negative, or neutral) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to our established performance standards with respect to the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for CY 2024 performance period/2026 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold we have established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. The actual amount paid to the MIPS eligible clinician in MIPS payment year, once the MIPS payment adjustment factor is applied, is subject to further calculations such as application of the scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to be subject to the MIPS reporting requirements and payment adjustment). Eligible clinicians who are QPs for the 2023 performance year receive a 3.5 percent APM Incentive Payment in the 2025 payment year, and, beginning with the 2024 performance year (payment year 2026), a higher PFS payment rate (calculated using the differentially higher ''qualifying APM conversion factor'') than non-QPs. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year.

As we move into the seventh year of the Quality Payment Program, we are

proposing the updates set forth in this section of this proposed rule, encouraging continued improvement in clinicians' performance with each performance year and drive improved quality of health care through payment policy.

In developing and putting forth these proposals, we intend to continue our efforts to align the Quality Payment Program with broader CMS initiatives, such as the establishment of the Universal Foundation (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*) and the CMS National Quality Strategy (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy*). These initiatives unify strategic efforts across our programs, including the Quality Payment Program, to adopt measures most critical to providing high quality care and accelerate strategic improvements for quality programs and measures.

The vision for the CMS National Quality Strategy is to shape a resilient, high-value American health care system to achieve high-quality, safe, equitable, and accessible care for all. This strategy aims to promote the highest quality outcomes and safest care for all individuals. It also focuses on a person-centered approach as individuals journey across the continuum of care, care settings, and across payer types. The goals of this strategy incorporate lessons learned from the COVID–19 public health emergency (PHE) to inform both short and long-term direction for our health care system.

The Universal Foundation moves toward a building-block approach to advance the overall vision of the National Quality Strategy and increase alignment across CMS quality programs by capturing measures that are meaningful, broadly applicable, and capable of being digitally reported and stratified, in order to identify and track disparities over time. The Universal Foundation seeks to improve health outcomes, reduce provider burden, improve standardization of measurement, and promote interoperability by prioritizing measures to transition to interoperable digital data.

The implementation of MIPS Value Pathways (MVPs) aligns with many of the objectives and goals the CMS National Quality Strategy and the Universal Foundation strive to achieve. For example, in an effort to align implementation of the measures in the Universal Foundation across MIPS and APMs, we are proposing updates to consolidate the Promoting Wellness and Managing Chronic Conditions MVPs to align with the adult Universal Foundation measure set. We are also exploring the expansion of the APM Performance Pathway (APP) reported by clinicians in the Shared Savings Program and Advanced APMs to include the primary care universal measure set in the future. In our continued strategy to incentivize improved equity as well as advancing value, in Performance Year 2023 the Shared Savings Program will implement an upside-only adjustment to reward ACOs that provide excellent care for underserved populations (87 FR 69838 through 69857). In our goal to accelerate interoperability, we propose to require Shared Savings Program ACO clinicians to report the measures and objectives required by the MIPS Promoting Interoperability performance category. We are also proposing to modify our CEHRT use criterion for Advanced APMs to promote flexibility in adopting CEHRT that is clinically relevant to participants, emphasizing the importance of interoperability and health information technology. Moreover, we propose to expand our portfolio of available MVPs for the CY 2024 performance period and remain committed to our goal of ensuring more meaningful participation in the Quality Payment Program through MVPs.

b. Summary of Major Provisions

(1) Transforming the Quality Payment Program

The CMS National Quality Strategy addresses the urgent need for transformative action to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. This vision is supported by the alignment of policies and quality measures in MIPS and APMs within the Quality Payment Program. Priorities for the Quality Payment Program include: achieving more equitable outcomes; utilizing clinically relevant measures for specialty performance that inform clinicians and beneficiaries; enhancing quality, patient safety, and efficiency through use of certified EHR technology (CEHRT); reducing burden and simplifying quality performance reporting; articulating meaningful outcomes, promoting alignment where possible, and moving to all digital reporting.

The Quality Payment Program allows eligible clinicians to engage in patient-centered care via two tracks: the Merit-Based Incentive Program (MIPS) and APMs. We believe the Quality Payment Program should continuously support the measurement and improvement of specialty and primary care. To this end, we are implementing MVPs to allow clinicians to report on measures that are directly relevant to their clinical practice. MVPs provide more clinically relevant performance measurement, engage more specialists in performance measurement, and reduce barriers to APM participation. CMS has recently laid out multiple steps intended to fulfill the potential of APMs. The CMS Innovation Center strategy refresh acknowledges that whole person care requires the depth and scope of services that includes both primary and specialty care and aims to provide ACOs with tools to better engage specialists, test ways to better link primary and specialty care upstream in the patient journey, and further movement into value-based care.[296]

(2) Major MIPS Provisions

We are requesting comment on how the Quality Payment Program can facilitate continuous improvement of Medicare beneficiaries' healthcare and best build on existing CMS Innovation Center model policies and Medicare programs, such as the Medicare Shared Savings Program. We are seeking feedback on how we might modify our policies, requirements, and performance standards to encourage clinicians to continuously improve the quality of care, particularly for clinicians with little room for improvement in MIPS.

(a) MIPS Value Pathways Development and Maintenance

In an effort to promote high-quality, safe, and equitable care and to implement the vision outlined in the CMS National Quality Strategy, we are proposing five new MVPs around the topics of: Women's Health; Infectious Disease, Including Hepatitis C and HIV; Mental Health and Substance Use Disorder; Quality Care for Ear, Nose, and Throat (ENT); and Rehabilitative Support for Musculoskeletal Care. In addition, we are proposing MVP maintenance updates to our MVP inventory that are in alignment with the MVP development criteria, and in consideration of the feedback from interested parties we have received through the maintenance process.

(b) Subgroup Reporting

We are proposing to codify previously finalized subgroup policies in the preamble to regulation text. Additionally, we are proposing updates

[296] CMMI Strategy Refresh. October 20, 2021. *https://innovation.cms.gov/strategic-direction-whitepaper.*

to previously finalized subgroup policies to help guide clinicians and groups to meaningfully participate in MVPs through subgroup reporting. Specifically, we are proposing to update the subgroup policy for reweighting of MVP performance categories, update the facility-based scoring as well as the complex patient bonus for subgroups under final score calculation, and add subgroups to the targeted review regulation text.

(c) MIPS Performance Category Measures and Activities

(i) Quality Performance Category

We are proposing six modifications to the quality performance category. First, we propose to expand the definition of the collection type to include Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs). Second, we propose to establish the quality performance category data submission criteria for eCQMs that requires the utilization of CEHRT. Third, we propose to establish the data submission criteria for Medicare CQMs. Fourth, we propose to require the administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey in the Spanish translation. Fifth, we propose to maintain the data completeness criteria threshold to at least 75 percent for the CY 2026 performance period/2028 MIPS payment year, and increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year. Sixth, we propose to establish the data completeness criteria for Medicare CQMs. Finally, we propose to establish a measure set inventory of 200 MIPS quality measures.

(ii) Cost Performance Category

We are proposing to add five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. These five proposed measures are Depression, Emergency Medicine, Heart Failure, Low Back Pain, and Psychoses and Related conditions; several of these have relevance to the CMS Behavioral Health Strategy (*https://www.cms.gov/cms-behavioral-health-strategy*). We are proposing to use a 20-episode case minimum for each of these new measures, and are requesting comments on our clarification of the indented interpretation of the language on the case minimums codified at § 414.1350(c). We are also proposing to remove the Simple Pneumonia with Hospitalization episode-based measure beginning with the CY 2024 performance period/2026 MIPS payment year. Finally, we are proposing to update the operational list of care episode and patient condition groups and codes to add all five new measures and remove the Simple Pneumonia with Hospitalization episode-based measure from the operational list of care episode and patient condition groups and codes.

(iii) Improvement Activities Performance Category

We are proposing to add five new, modify one existing, and remove three existing improvement activities from the Inventory. The new and modified activities help fill gaps we have identified in the Inventory as well as seek to ensure that activities reflect current clinical practice across the category. Four of the new activities being proposed relate to CMS Health Equity, Increase All Forms of Accessibility to Health Care Services and Coverage. We are also recommending the removal of three activities, both to align with current clinical guidelines and practice as well as to eliminate duplication, so that the Inventory offers flexibility and choice without potentially causing burden with too many activities to choose from.

(iv) Promoting Interoperability Performance Category

We are proposing five policy modifications for the Promoting Interoperability performance category. Specifically, we propose to: (1) lengthen the performance period for this category from 90 days to 180 days; (2) modify one of the exclusions for the Query of Prescription Drug Monitoring Program (PDMP) measure; (3) provide a technical update to the e-Prescribing measure's description to ensure it clearly reflects our previously finalized policy; (4) modify the Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guide measure to require MIPS eligible clinicians to affirmatively attest to completion of the self-assessment of their implementation of safety practices; and (5) continue to reweight this performance category at zero percent for clinical social workers for the CY 2024 performance period/2026 MIPS payment year. In section III.R.2.b. of this proposed rule, we are proposing to revise our regulatory definition of CEHRT for the Promoting Interoperability performance category to be more flexible in reflecting any changes the Office of the National Coordinator for Health Information Technology (ONC) may make to its Base EHR definition, certification criteria, and other standards for health information technology.

(d) MIPS Final Scoring Methodology

(i) Performance Category Scores

We are proposing updates to our scoring flexibilities policy. We are proposing to update the criteria by which we assess the scoring impacts of coding changes and apply our scoring flexibilities. We are also proposing that eCQM measure specifications would be required to include the ability to be truncated to a 9-month performance period.

(ii) Cost Improvement Scoring

We are proposing two modifications to the cost improvement scoring method that was established in the CY 2018 Quality Payment Program final rule. First, we are proposing to change improvement scoring from a measure-level to a category-level method and to remove the statistical significance requirement. Second, we are proposing that the maximum cost improvement score is zero percentage points for the 2020 through 2024 MIPS payment years, and one percentage point beginning with the CY 2023 performance period/2025 MIPS payment year.

(e) MIPS Payment Adjustments

We are proposing to revise our policy for identifying the ''prior period'' by which we will establish the performance threshold beginning with the CY 2024 performance period/2026 MIPS payment year. Specifically, we are proposing to define the ''prior period'' by which we establish the performance threshold as three performance periods, instead of a single prior performance period, and codify this policy at § 414.1405(g)(2). To determine the performance threshold for the CY 2024 performance period/2026 MIPS payment year, we are proposing to use the CY 2017/2019 MIPS payment year through CY 2019 performance period/2021 MIPS payment year as the prior period. Based on the mean final score from that prior period, we are proposing to establish the performance threshold as 82 points for the CY 2024 performance period/2026 MIPS payment year.

(f) MIPS Targeted Review

We are proposing to add virtual groups and subgroups as being eligible to submit a request for targeted review. We are proposing to codify this addition at § 414.1385(a).

We are proposing to amend at § 414.1385(a)(2) with respect to the

timeline for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM entities to request a targeted review of our calculation of their MIPS payment adjustment factor(s). Specifically, we are proposing to permit submission of a request for targeted review beginning on the day we make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. This proposal would modify the current time period to submit a request for targeted review, which is 60 days beginning on the day that CMS makes available the MIPS payment adjustment factors for the MIPS payment year.

We also are proposing to amend § 414.1385(a)(5). Specifically, we are proposing to require that, if CMS requests additional information under the targeted review process, then that additional information must be provided to and received by CMS within 15 days of receipt of such request. This proposal would modify the current timeline to respond to CMS' request set forth at § 414.1385(a)(5), which is within 30 days of receipt of such request.

(g) Third Party Intermediaries

In this proposed rule, in addition to codifying previously finalized policies and proposing to make technical updates for clarity, we propose to: (1) Add requirements for third party intermediaries to obtain documentation of their authority to submit on behalf of a MIPS eligible clinician; (2) Specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (3) Add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) Add a requirement for QCDRs and qualified registries to attest that the information contained in the qualified posting about them is correct; (5) Modify requirements for QCDRs and qualified registries to support MVP reporting to increase flexibility for measures supported; (6) Specify requirements for a transition plan for QCDRs and qualified registries withdrawing from the program; (7) Specify requirements for data validation audits; (8) Add additional criteria for rejecting QCDR measures; (9) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) Eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify the process for publicly posting remedial action; and (14) Specify the criteria for audits.

(h) Public Reporting on Compare Tools

In an effort to expand the information available to patients and caregivers when choosing a doctor or clinician, we are proposing to modify the existing policy for public reporting on individual clinician and group profile pages, including proposals to revise:

- The telehealth indicator, such that, we would use the most recent CMS coding policies at the time the information is updated to identify the telehealth services provided on clinician profile pages instead of only using specific Place of Service (POS) and claims modifier codes.
- Utilization data, such that we have additional procedure code grouping flexibility; can address procedure volume limitations and provide a more complete scope of a clinician's experience by adding Medicare Advantage (MA) data to procedure counts; and align the data in the Provider Data Catalog (PDC) with the procedural groupings shown on profile pages.

Additionally, we solicit feedback from interested parties through a request for information on ways to publicly report data submitted on measures under the MIPS cost performance category on the Compare tool.

(3) Major APM Provisions

(a) APM Performance Pathway

In section IV.A.4.e. of this proposed rule, we are proposing to include the Medicare Clinical Quality Measure (Medicare CQM) for Accountable Care Organizations Participating in the Medicare Shared Savings Program collection type in the APM Performance Pathway (APP) measure set.

(b) Overview of the APM Incentive

In section IV.A.4.m. of this proposed rule, we are proposing to end the use of APM Entity-level QP determinations and instead make all QP determinations at the individual eligible clinician level. We are also proposing to modify the ''sixth criterion'' under the definition of ''attribution-eligible beneficiary,'' which is listed at § 414.1305.[297] Specifically, we are proposing to include any beneficiary who has received a covered professional service furnished by the NPI for the purpose of making QP determinations. We are also proposing to amend § 414.1430 to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count methods under the Medicare Option and the All-Payer Option with respect to payment year 2025 (performance year 2023) in accordance with amendments made by the CAA, 2023. Relatedly, we are proposing to amend § 414.1450 to reflect the statutory APM Incentive Payment amount for the 2025 payment year (performance year 2023) of 3.5 percent of the eligible clinician's estimated aggregate payments for covered professional services in accordance with amendments made by the CAA, 2023. In section IV.A.4.j. of this proposed rule, we are proposing to amend § 414.1385 to adjust the Targeted Review period to address operational challenges that have arisen ahead of the required transition beginning for payment year 2026 (performance year 2024) from the APM Incentive Payment to the higher PFS payment rate for QPs (calculated using the differentially higher ''qualifying APM conversion factor).

(c) Advanced APMs

In section IV.A.4.n. of this proposed rule, we are proposing to modify the CEHRT use criterion for Advanced APMs to provide greater flexibility for APMs to tailor CEHRT use requirements to the APM and its participants. We are proposing to amend the CEHRT use criterion for Advanced APMs at § 414.1415(a)(1)(i) effective beginning for CY 2024 to no longer apply the 75 percent CEHRT use minimum, and to instead specify that the APM must require all APM participants to use CEHRT as defined in a proposed revised definition of CEHRT under § 414.1305. We are also proposing to amend the Other-Payer Advanced APM CEHRT use criterion at § 414.1420(b) to conform to the proposed changes at § 414.1415(a)(1)(i).

[297] Currently, there are six criteria required for a beneficiary to be an ''attribution-eligible beneficiary'' during the QP Performance Period, which can be found at § 414.1305. The sixth criterion provides that an ''attribution-eligible beneficiary'' must have ''a minimum of one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on evaluation and management services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for evaluation and management services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of evaluation and management and/or other services.''

2. Definitions

At § 414.1305, we are proposing to revise the definitions of the following terms:

- Attribution-eligible beneficiary;
- Certified Electronic Health Record Technology (CEHRT); and
- Collection type.
- Qualified posting

These terms and definitions are discussed in detail in the relevant sections of this proposed rule.

3. Transforming the Quality Payment Program

a. Advancing CMS National Quality Strategy Goals

(1) Increasing Alignment Across Value-Based Programs

The CMS National Quality Strategy [298] addresses the urgent need for transformative action to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. One of the CMS National Quality Strategy goals is to improve quality and health outcomes across the health care journey through implementation of a ''Universal Foundation'' of impactful measures across all CMS quality and value-based programs.[299] Adoption of the Universal Foundation [300] [301] will focus clinician attention on specific quality measures, reduce burden, help identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.

We identified adult and pediatric measures for the Universal Foundation to be used across CMS programs and populations, including the Quality Payment Program, to the extent they are applicable. The Quality Payment Program measure inventory already includes quality measures in the adult core set from the Universal Foundation. In addition, we propose in this proposed rule to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP that aligns with the adult Universal Core set of quality measures. We refer readers to section IV.A.4.b. and Appendix 3: MVP Inventory, Table B.11 of this proposed rule for our proposed updates to the Promoting Wellness and Chronic Disease Management MVPs. We will continue to identify additional measures, which may be included in future MVPs, to capture aspects of specialist quality in the Universal Foundation.[302] We also refer readers to section III.G.2.c. of this proposed rule for discussions on expanding the APM Performance Pathway (APP) reported by clinicians in the Shared Savings Program and Advanced APMs to include Medicare Clinical Quality Measure (Medicare CQM) collection types and further alignment with the Universal Foundation.

(2) Advancing Health Equity

We also articulated a detailed strategy to advance health equity and accountability in order to design, implement, and operationalize policies to support health for all people served by our programs, eliminate avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and provide the care and support that our beneficiaries need to thrive.[303] Specifically, the CMS Office of Minority Health released the *CMS Framework for Health Equity,*[304] which updates the CMS Equity Plan with an enhanced and more comprehensive 10-year approach to further embed health equity across CMS programs including Medicare, Medicaid, Children's Health Insurance Program, and the Health Insurance Marketplaces. The CMS Office of Minority Health also released Paving the Way to Equity: A Progress Report [305] in 2021, which describes the CMS Equity Plan for Medicare and progress from 2015 to 2021.

In accordance with our health equity strategy, both MVPs and APMs share a goal of incenting improved equity as well as advancing value (87 FR 70035). For example, beginning in Performance Year 2023 the Shared Savings Program will implement an upside-only Health Equity Adjustment (HEA) to an ACO's MIPS Quality performance category score to reward ACOs that provide excellent care for underserved populations (87 FR 69838 through 69857).

(3) Accelerating Interoperability

The CMS National Quality Strategy also calls for supporting the transition to a digital and data driven health care system. The CMS National Quality Strategy proposed to achieve this through the development of requirements for sharing, receipt, and use of digital data, including digital quality measures.[306] We believe that, as clinicians strive to make improvements in patient care, clinicians should demonstrate increasingly more advanced and innovative uses of health information technology. In section III.G.2.h. of this proposed rule, we propose to require Shared Savings Program ACO clinicians to report the measures in the MIPS Promoting Interoperability performance category. Additionally, in section III.G.2.h.(2) of this proposed rule, we propose to modify our requirements for use of CEHRT for Advanced APMs to promote flexibility in adopting CEHRT that is clinically relevant to participants, emphasizing the importance of interoperability and health information technology. We believe these proposals, in addition to ongoing efforts to build CMS infrastructure and develop technical solutions, are an important step towards evolving our health information technology ecosystem.

b. Quality Payment Program Vision and Goals

(1) Emphasizing the Importance of Value-Based Care

The Quality Payment Program was designed and implemented to improve health outcomes, promote smarter spending, minimize burden of participation, and provide fairness and transparency in operations (81 FR 77010). The Quality Payment Program allows for eligible clinicians to engage in value-based, patient-centered care via

[298] The National Quality Strategy: A Person-Centered Approach to Improving Quality . . ., *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality*.

[299] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[300] Aligning Quality Measures across CMS. *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation*.

[301] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*. CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[302] Aligning Quality Measures across CMS—The Universal Foundation. Jacobs, Schreiber, Seshamani, Tsai, Fowler, and Fleisher. *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

[303] CMS National Quality Strategy. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[304] CMS Equity Plan for Improving Quality in Medicare. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf*.

[305] CMS, Paving the Way to Equity: A Progress Report (2015–2021) *https://www.cms.gov/sites/default/files/2021-01/Paving%20the%20Way%20to%20Equity%20CMS%20OMH%20Progress%20Report.pdf*.

[306] CMS National Quality Strategy. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/cms-quality-strategy*.

two tracks: the Merit-Based Incentive Program (MIPS) and Advanced Alternative Payment Models (APMs). MIPS encourages collection and submission of data for evidence-based, specialty-specific quality measures, completion of practice-based improvement activities, consideration of cost measures, and use of certified electronic health record (EHR) technology (CEHRT) to support interoperability (81 FR 77010). APMs are models operating under section 1115A of the Act, the Shared Savings Program under section 1899 of the Act (that is, Accountable Care Organizations), or a demonstration under section 1866C or required by Federal law. In the Advanced APM track of the Quality Payment Program, APM entities and eligible clinicians take responsibility for improving the quality of care, care coordination and health outcomes for a group of beneficiaries through participation in Advanced APMs.[307] Advanced APMs can ensure that beneficiaries get the right care at the right time by reducing fragmentation between clinicians, which can reduce unnecessary duplication of services and preventable medical errors.[308] Advanced APMs also support our goal that all Traditional Medicare beneficiaries be in a care relationship with clinicians accountable for quality and total cost of care by 2030, as outlined by the CMS Innovation Center strategy refresh.[309]

CMS recently established, and is implementing, various strategies that are intended to fulfill the potential of Advanced APMs. The CMS Innovation Center strategy refresh acknowledges that whole person care requires the depth and scope of services that includes both primary and specialty care, and aims to provide Accountable Care Organizations (ACOs) with tools to better engage specialists, test ways to better link primary and specialty care upstream in the patient journey, and further movement into value-based care.[310] Our ongoing alignment of the Shared Savings Program and the Quality Payment Program supports new as well as long term participation in ACOs for clinicians choosing to participate in accountable care relationships. In the CY 2021 PFS final rule, we finalized the Alternative Payment Model (APM) Performance Pathway (APP) under MIPS, in part, to reduce reporting burden, and create new scoring opportunities for MIPS eligible clinicians participating in MIPS APMs (85 FR 84720).

(2) MVP Reporting in the Quality Payment Program

We believe the Quality Payment Program should continuously support the measurement and improvement of specialty and primary care practice. To this end, we are implementing MVPs in MIPS to allow for clinicians to report on measures that are directly relevant to their clinical practice. Rather than selecting individual measures and activities from a large inventory to report under each of the siloed MIPS performance categories under traditional MIPS, eligible clinicians who select an MVP (for example, the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP) can select from a smaller, cohesive set of measures and activities focused on the clinician's performance in rendering care for their specialty or clinical condition.

We also developed MVPs with the intention to support clinicians in their journey of continuous performance improvement and to reduce barriers to APM participation as clinicians and practices prepare to take on, and successfully manage financial risk (84 FR 62946 through 62949).

c. Promoting Continuous Improvement in MIPS

For the MIPS program, we developed policies and methodologies to assess clinicians' performance, and to support performance improvement across four performance categories (quality, cost, improvement activities, and Promoting Interoperability) in accordance with section 1848(q)(1)(A)(i) and (ii) of the Act. We believe we should evaluate our policies, requirements, and standards for MIPS periodically to determine if we need to raise the bar in order to foster the availability of opportunities for continuous performance improvement. We are considering how we can implement policies to support continuous improvement for clinicians who consistently perform well in MIPS. One challenge we face is that, after a clinician has achieved high performance scores on the same measures and activities year over year, there may be little or no room for the clinician to improve their performance. Another challenge is that some MIPS eligible clinicians choose measures and activities on which that they are already performing well, rather than measures and activities where they would be required to implement changes in their workflow, clinical care, or practices in order to achieve a positive payment adjustment. This selection practice, to repeatedly choose the same measures and activities on which the clinician is confident they will perform well, can mean that the clinician has less incentive to transform the way that care is delivered and continuously improve quality of the care they provide. For these reasons, we are considering modifying our policies to encourage clinicians who have consistently been high performers in MIPS to continuously improve various areas of their clinical practice, including implementing more rigorous standards under MIPS and supporting participation in an APM.

We are interested in feedback on approaches to modifying our policies, requirements, and standards under MIPS, while remaining cognizant of the burden any changes may place on MIPS eligible clinicians. Section 1848(q)(1)(A) and (5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for applicable measures and activities in each performance category applicable to the MIPS eligible clinician for a performance period. We are particularly interested in how we can balance the impact of any policy changes on MIPS eligible clinicians who have become accustomed to our current program requirements with the benefit of potential modifications that foster clinicians' continuous improvement. For example, we could increase reporting requirements in traditional MIPS and MVPs, or we could require that specific measures be reported, instead of allowing choice of measures, once MVPs are mandatory to encourage improvement for clinicians with continuously perform well under MIPS.

d. Request for Feedback

We are seeking comment on how we can modify our policies under the Quality Payment Program to foster clinicians' continuous performance

[307] Medicare Value-Based Care Strategy: Alignment, Growth and Equity. The Medicare Value-Based Care Strategy: Alignment, Growth, And Equity. Health Affairs, Jacobs, Fowler, Fleisher, and Seshamani. *https://www.healthaffairs.org/content/forefront/medicare-value-based-care-strategy-alignment-growth-and-equity*.

[308] CMS Announces Increase in 2023 in Accountable Care Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship. *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable*.

[309] Innovation Center Strategy Refresh. *https://innovation.cms.gov/strategic-direction-whitepaper*.

[310] CMMI Strategy Refresh. October 20, 2021. *https://innovation.cms.gov/strategic-direction-whitepaper*.

improvement and positively impact care outcomes for Medicare beneficiaries. Such modifications for MIPS may include requiring more rigorous performance standards, emphasizing year-to-year improvement in the performance categories, or requiring that MIPS eligible clinicians report on different measures or activities once they have demonstrated consistently high performance on certain measures and activities.

In accordance with implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation request for information is exempt from the PRA.

We request public comment on specifically the following questions:

- What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?
- Should we consider, in future rulemaking, changes in policies to assess performance to ensure ongoing opportunities for continuous performance improvement?
- Should we consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?
- Should we consider creating additional incentives to join APMs in order to foster continuous improvement, and if so, what should these incentives be?
- What changes to policies should CMS consider to assess continuous performance improvement and clinicians interested in transitioning from MIPS to APMs?
- We acknowledge the potential increase in burden associated with increasing measure reporting or performance standards. How should we balance consideration of reporting burden with creating continuous opportunities for performance improvement?
- While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

4. MVP Development, Maintenance, and Scoring

a. Development of New MIPS Value Pathways (MVPs)

In the in the CY 2023 PFS final rule (87 FR 70035 and 70037), we finalized modifications to our MVP development process to include feedback from the general public before the notice and comment rulemaking process. We will evaluate a submitted candidate MVP through the MVP development process, and if we determine it is ''ready'' for feedback, we would post a draft version of the submitted candidate MVP on the Quality Payment Program (QPP) website (*https://qpp.cms.gov*) and solicit feedback for a 30-day period. The general public would have the opportunity to submit feedback on the candidate MVP for CMS's consideration through an email inbox. We stated that we would review the feedback received, and determine if any changes should be made to the candidate MVP prior to potentially including the MVP in a notice of proposed rulemaking. If we determine changes should be made to the candidate MVP, we would not notify the interested parties who originally submitted the candidate MVP for CMS consideration in advance of the rulemaking process. We refer readers to the MVP Candidate Feedback Process web page, available on the Quality Payment Program website, to review the public feedback we received for each candidate MVP (*https://qpp.cms.gov/mips/candidate-feedback*).

Through our development processes for new MVPs (*see* 85 FR 84849 through 84856, 87 FR 70035 through 70037), we aim to gradually develop new MVPs that are relevant and meaningful for all clinicians who participate in MIPs. In this proposed rule, we are proposing the inclusion of five new MVPs:

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disease Including Hepatitis C and HIV;
- Quality Care in Mental Health and Substance Use Disorder;
- Quality Care for Ear, Nose, and Throat (ENT); and
- Rehabilitative Support for Musculoskeletal Care

We continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*. We refer readers to Appendix 3: MVP Inventory, in this proposed rule for discussion of each proposed new MVP.

b. MVP Maintenance on Previously Finalized MVPs

In the CY 2023 PFS final rule (87 FR 70037), we finalized a modification to the annual maintenance process for MVPs that were previously adopted through notice and comment rulemaking (86 FR 65410). Interested parties and the general public may submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. We would then review the submitted recommendations and determine whether any are potentially feasible and appropriate. We stated that if we identify any submitted recommendations that are potentially feasible and appropriate, we would host a public facing webinar, open to interested parties and the general public through which they may offer their feedback on the potential revisions we have identified. We would publish details related to the timing and registration process for the webinar through our Quality Payment Program Listserv. We held our first MVP maintenance webinar in February 2023 (*https://youtu.be/4cuZGUr88SA*), to discuss any feedback we received from interested parties regarding previously finalized MVPs.

In the CY 2022 PFS final rule (86 FR 65998 through 66031), we finalized seven MVPs that are available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Advancing Rheumatology Patient Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Advancing Care for Heart Disease;
- Optimizing Chronic Disease Management;
- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Improving Care for Lower Extremity Joint Repair; and
- Patient Safety and Support of Positive Experiences with Anesthesia.

In addition, in the CY 2023 PFS final rule (87 FR 70037), we finalized five additional MVPs that are available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Advancing Cancer Care;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Supportive Care for Cognitive-Based Neurological Conditions; and
- Promoting Wellness.

In this proposed rule, we are proposing modifications to these twelve

MVPs to propose the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854), feedback received through the MVP maintenance process, and based off the proposed removals of certain improvement activities from the improvement activities inventory and the proposed addition of other relevant existing quality measures for MVP participants to select from. In addition, through the MVP maintenance process, we are proposing to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP, that aligns with the Adult Universal Core Set, as described in the journal article, ''*Aligning Quality Measures across CMS—The Universal Foundation*'' (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*). (*https://www.nejm.org/doi/full/10.1056/NEJMp2215539*). We refer readers to Appendix 3: MVP Inventory of this final rule for the proposed modifications to the established MVPs.

c. Scoring MVP Performance

In the CY 2022 PFS final rule, we finalized policies for MVP scoring that take effect beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to 86 FR 65419 through 65427 for the details of those finalized policies. We previously finalized at § 414.1365(d)(2) that, unless otherwise indicated in § 414.1365(d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 65419 through 65421). We noted that in general, we intend to adopt scoring policies from traditional MIPS for MVP participants unless there is a compelling reason to adopt a different policy to further the goals of the MVP framework (86 FR 65419).

We refer readers to section IV.A.4.g.(1)(c)(i) of this proposed rule for proposed policies on MIPS scoring flexibilities in the quality performance category scoring; section IV.A.4.g.(1)(d)(i) in this proposed rule for the proposed change to scoring improvement in the cost performance category; section IV.A.4.f.(3)(b) and Appendix 2: Improvement Activities, of this proposal rule for the proposed improvement activity ''IA_MVP, Practice-wide quality improvement in the MIPS Value Pathway Program (MVP)'' in the improvement activities performance category; section IV.A.4.f.(4) in this proposed rule for the proposed policies for the Promoting Interoperability performance category, including modifications of the SAFER Guide Measure's requirements and the Query of Prescription Drug Monitoring Program (PDMP) measure's exclusion, a technical update to the e-Prescribing measure, an increase in the length of the performance period from 90 continuous days to 180 continuous day, and continuation of our reweighting policy of the performance category for clinical social workers.

In addition, we refer readers to section IV.A.4.d. of this proposed rule for proposed policies regarding subgroups, including reweighting proposals, addition of subgroups to our Targeted Review policies, and a clarification regarding the scoring of facility-based clinicians at the subgroup level.

We refer readers to section IV.A.4.j. of this proposed rule for proposed policies regarding Targeted Review process, including the addition of virtual groups to our Targeted Review policies.

d. Subgroup Reporting

(1) Background

In the CY 2022 PFS final rule, we finalized the option for clinicians to participate as subgroups for reporting MIPS value pathways (MVPs) beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to Title 42 of the Code of Federal Regulations (CFR) at §§ 414.1318 and 414.1365, the CY 2022 PFS final rule (86 FR 65398 through 65405), and the CY 2023 PFS final rule (87 FR 70038 through 70045) for additional details on previously finalized subgroup policies.

In this section, we are proposing to: (1) update the subgroup policy for reweighting of MVP performance categories at § 414.1365(e)(2); (2) update the facility-based scoring and complex patient bonus for subgroups under final score calculation at § 414.1365(e)(3) and (4); (3) update the targeted review policy for subgroups at § 414.1385; and (4) codify in our regulations the subgroup policies finalized in previous years' rules.

(2) Subgroup Reweighting

In the CY 2022 PFS final rule (86 FR 65425 through 65426), we finalized at § 414.1365(e)(2)(ii) that for an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. Additionally, we finalized that if reweighting is not applied to an affiliated group, then the subgroup may receive reweighting under the circumstances described at §§ 414.1365(e)(2)(ii)(A) and (B). In establishing this policy, we noted our concern about extreme and uncontrollable circumstances (EUC) that would impact only the subgroup (fire or natural disaster at a specific practice location) and does not affect the entire affiliated group. We also finalized that if a subgroup submits data for a performance category which was reweighted, the subgroup data submission will void the reweighting applied to the performance category.

Upon further consideration of the previously finalized policy, we identified technical constraints that affect our ability to implement the policy. Specifically, we are concerned that the time necessary to adjudicate reconsideration requests for both a subgroup and its affiliated group may deprive the subgroup of knowledge of its reweighting status during a significant portion of the relevant performance period and undermine its ability to plan data submission needs accordingly.

There may be instances when a subgroup and its affiliated group have separate reasons to submit reweighting applications. Those separate applications may request the reweighting of different performance categories. Under § 414.1380(c)(2), clinicians, groups, and APM Entities submit reweighting applications annually on a rolling basis throughout the performance period, or a date specified by CMS. However, the requirement in § 414.1365(e)(2)(ii) that any reweighting applied to a subgroup's affiliated group is also applied to the subgroup means that when a subgroup and its affiliated group both submit reweighting applications, the subgroup will not know its reweighting status until CMS makes a determination regarding the group's reweighting application. Depending on when the group submitted its reweighting request, this may not happen until after the close of the performance period for which the reweighting application was made.

We believe the uncertainty created for a subgroup by not knowing its reweighting status until later in the performance period would disrupt its ability to best plan for the measures and activities on which it will be scored. We recognize that there may be instances when only the subgroup is affected by an extreme and uncontrollable circumstance (natural disaster, fire, hurricane, etc.) and would want to request its own reweighting, independent of the affiliated group. However, we believe that the need for a subgroup to know of its data submission requirements outweighs the

benefit of being able to request its own reweighting independent of the affiliated group.

Separately, there are certain special status designations (non-patient facing, small practice, etc.) that automatically qualify a group for reweighting of the Promoting Interoperability performance category. A subgroup can learn about its affiliated group's special status designation as described in the second paragraph under the definition of MIPS determination period at § 414.1305. Given that subgroup eligibility and special status determinations are made at the group level, we believe that applying an affiliated group's reweighting to a subgroup, and removing the ability of a subgroup to submit a separate reweighting application, would enable subgroups to receive their reweighting status and identify their data submission obligations in a timely manner. We are therefore proposing to revise § 414.1365(e)(2)(ii) to limit the reweighting applied to a subgroup to that which is also applied to its affiliated group beginning with the CY 2024 performance period/2026 MIPS payment year.

In order to operationalize the previously established policy, we intend to implement a manual process for reviewing subgroup reweighting applications for the CY 2023 performance period/2025 MIPS payment year. We considered also using the manual process for reviewing subgroup reweighting applications in future performance periods. However, we are concerned that manually reconciling the reweighting requests would delay the approval of the reweighting requests received from a subgroup. Additionally, we are concerned that it may create confusion for a subgroup to determine whether a performance category has been reweighted and its potential impact on subgroup data submission, specifically in instances when both the subgroup and its affiliated group submit a reweighting application for one or more of the MVP performance categories. For the above reasons, we would use the manual process only for the CY 2023 performance period/2025 MIPS payment year.

We acknowledge that there may be instances when an extreme and uncontrollable circumstance impacts only a subgroup and not the entire affiliated group (for example, fire or natural disaster at the subgroup's practice location). Because subgroup reporting is not mandatory at this time, we believe that in these instances, when a registered subgroup is unable to participate in MVP reporting as a subgroup, the eligible clinicians in the registered subgroup would participate in MIPS via another available reporting option. These clinicians could either participate as individuals or as a group, if its affiliated group chooses to participate in traditional MIPS, or in MVP reporting. Additionally, we established the policy in § 414.1318(b)(1) to not assign a score for a registered subgroup that did not submit data for the applicable performance period (87 FR 70045). In the scenario that the registered subgroup did not submit data, we would assign the highest of the available final scores associated with the clinician's TIN/NPI for the eligible clinicians in the subgroup (86 FR 65536 and 65537). We refer readers to the CY 2023 PFS proposed rule (87 FR 46272 through 46275) for examples that illustrate how the final score is applied for a clinician who is part of a group TIN where only some of the clinicians under that TIN choose to participate in MIPS through subgroups. We will continue to monitor subgroup participation trends and will revisit this policy in the future, as needed.

For the above reasons, we are proposing to revise § 414.1365(e)(2)(ii) to state that an MVP Participant that is a subgroup will receive the same reweighting that is applied to its affiliated group, but that for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the circumstances independent of the affiliated group as described in § 414.1365(e)(2)(ii)(A) and (B).

We request comments on this proposal.

(3) Subgroup Scoring Policies

(a) Facility-Based Score for Subgroups

We established policies for facility-based measurement and scoring for MIPS eligible individual clinicians and groups at § 414.1380(e). Under these standards, we calculate a MIPS eligible clinician's final facility-based score using the clinician's performance in another value-based purchasing program (83 FR 59866 through 59867). In the CY 2022 PFS final rule (86 FR 65425), we finalized at § 414.1365(e)(3) that if an MVP Participant that is not an APM Entity is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). We recognize that we inadvertently overlooked excluding MVP Participants that are subgroups from facility-based scoring. We note that it was not our intent to calculate a facility-based score at the subgroup level.

In the course of implementing MVPs, we have offered clinicians and groups the opportunity to elect to report via MVPs and via traditional MIPS. If a facility-based MIPS eligible clinician participates in MVP reporting as an individual or as part of a group, we will calculate a final score for the MIPS eligible clinician based on the MVP reporting. We would not use the facility-based scores to calculate the clinician's final scores under the MVP because we currently do not have an MVP specifically focused on facility-based measurement. We believe eligible clinicians would choose to participate in MVP reporting with the intent to report on measures applicable to the scope of care provided and therefore, it would be appropriate for facility-based clinicians participating in MVP reporting to receive a score based on the data submitted for the measures and activities in an MVP. We would also calculate a score for traditional MIPS for this clinician or group and assign the higher of the scores. If a facility-based clinician chooses to participate in MVP for a MIPS performance period, a facility-based score would be calculated as part of traditional MIPS and not as part of MVP reporting. Subgroup reporting is limited to MVPs, and subgroup reporting is not available for clinicians reporting on measures in traditional MIPS. Therefore, we are proposing to modify the text at § 414.1365(e)(3) to state that if an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring a facility-based score will also be calculated in accordance with § 414.1380(e).

We are requesting comments on this proposal.

(b) Complex Patient Bonus for Subgroups

In the CY 2018 Quality Payment Program final rule (82 FR 53776), we finalized at § 414.1380(c)(3)(i) that we will add a complex patient bonus to the final score of certain MIPS eligible clinicians that submit data on at least one performance category during the applicable performance period. We finalized that this complex patient bonus would be calculated on the basis of the average Hierarchical Condition Category (HCC) risk score and the dual eligible ratio for beneficiaries seen by clinicians and groups. In the CY 2022 PFS final rule (86 FR 65425), we finalized at § 414.1365(e)(4) that a complex patient bonus will be added to the final score for an MVP Participant in

accordance with § 414.1380(c)(3). We also revised § 414.1380(c)(3) to permit subgroups to receive the complex patient bonus as, in the case of subgroups, we intended to apply the bonus based on the patient population of the subgroup.

Since then, however, we have identified issues with using claims data associated with the clinicians in a subgroup that prevents us from calculating the complex patient bonus at the subgroup level. Specifically, we are unable to identify the beneficiaries seen by the clinicians in a subgroup, and therefore we cannot calculate the average HCC score and dual eligible ratio scores. At the time the relevant claims data is retrieved, the composition of the subgroup may not be known, making it impossible to calculate the required data elements for the complex patient bonus (for example, clinicians, beneficiaries that received care, etc.) at the subgroup level. Additionally, the group may have subgroups that do not collectively represent the entire group, restricting our ability to gather the beneficiary data necessary to calculate the complex patient bonus score at the subgroup level.

We recognize that we would need to retroactively modify the previously established policy at § 414.1365(e)(4) for the CY 2023 performance period/2025 MIPS payment year to address the fact that we cannot calculate the complex patient bonus at the subgroup level. Section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because the current rule provides for the calculation of the complex patient bonus score at the subgroup level when it would be impossible for CMS to do so. For the reason stated previously in this section, we are proposing to add § 414.1365(e)(4)(i) to provide that for subgroups, beginning with the CY 2023 performance period/2025 MIPS payment year, the affiliated group's complex patient bonus will be added to the final score. Additionally, we are proposing conforming changes in § 414.1380(c)(3)(v) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, APM Entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. Similarly, we are proposing conforming changes in § 414.1380(c)(3)(vi) by removing the term ''subgroups'' so that beginning with the CY 2022 performance period/2024 MIPS payment year, for MIPS eligible clinicians and groups, the complex patient bonus components are calculated as described under § 414.1365(c)(3)(vi).

We are requesting comments on this proposal.

(4) Targeted Review for Subgroups

We previously established at § 414.1385(a) that a MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year (81 FR 77353 through 77358 and 77546). We also finalized the process to submit a targeted review application, codified at § 414.1385(a) (81 FR 77353 through 77358 and 77546). Similar to the previously established targeted review process for individual clinicians and groups, MIPS eligible clinicians who participate in MVP reporting and are scored as a subgroup may request a targeted review beginning with the CY 2023 performance period/2025 MIPS payment year. We recognize that we did not propose changes in the existing language for targeted review at § 414.1385(a) to reflect the availability of the targeted review process for subgroups. We are proposing to modify § 414.1385(a) to state that a MIPS eligible clinician, group, or subgroup may request a targeted review of the calculation of the MIPS payment adjustment factors applicable to such MIPS eligible clinician, group, or subgroup for a year. We are also proposing to modify § 414.1385(a)(1) to state that a MIPS eligible clinician, group or subgroup (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review. Additionally, we are proposing to make conforming changes at § 414.1385(a)(3), (5), and (6) to remove the term ''MIPS eligible clinician or group'' and add in its place the term ''MIPS eligible clinician, group, or subgroup.'' With these proposals, a subgroup that would like to request a review of the calculation for the MIPS payment adjustment factor for MVP data submission in the CY 2023 performance period/2025 MIPS payment year may also submit a targeted review application. We note that we are proposing additional changes to the targeted review process set forth in § 414.1385(a) as further described in section IV.A.4.j. of this proposed rule.

We are requesting comments on the above proposals.

(5) Codification of Previously Finalized Subgroup Policies From Preamble

We have identified that some subgroup policies were finalized in prior rulemaking but were not codified in the CFR. Additionally, we neglected to propose to include subgroups in our previously established definition of ''attestation'' in § 414.1305. We have reviewed the existing language and identified policies that should be codified. We now propose to correct these errors.

It is necessary for each of the proposed changes to the policies described below to be effective beginning with the CY 2023 performance period/2025 MIPS payment year in order for MIPS Value Pathways to operate effectively. Section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. Here, we believe that the failure to apply the proposed changes retroactively would be contrary to the public interest because the discrepancies remedied by the below proposals may cause undue confusion for clinicians participating as subgroups and may also create unintended errors in program implementation.

(a) Definitions

(i) Attestation

At § 414.1305, we currently define attestation to mean a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician or group may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS. Beginning in the CY 2023 performance period/2025 MIPS payment year, clinicians participating as subgroups would submit data for the Promoting Interoperability and improvement activities performance categories in an MVP as described at § 414.1365(c). As described previously in this section, we are proposing to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii). We believe that the failure to apply the proposed

change retroactively would be contrary to the public interest because it would create ambiguity in the requirement for a subgroup to submit data through an attestation for the Promoting Interoperability and improvement activities performance categories as described in § 414.1365(c). Therefore, we are proposing to add the term ''subgroup'' and revise the definition of attestation in § 414.1305 to state that attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician, group, or subgroup may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

We are requesting comments on this proposal.

(ii) Submitter Type

At § 414.1305, we defined a submitter type to mean the MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, or APM Entity, as applicable, that submits data on measures and activities under MIPS. In accordance with the subgroup reporting requirements at § 414.1318(c), we inadvertently overlooked adding subgroups in the definition of submitter type at § 414.1305. As described previously in this section, we are proposing to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii). We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because it would create ambiguity in the requirement for a subgroup to submit data as described at § 414.1318(c). Therefore, we are proposing to add the term ''subgroup'' and revise the definition of submitter type at § 414.1305 to state that a submitter type means the MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, subgroup, or APM Entity, as applicable, that submits data on measures and activities under MIPS.

We are requesting comments on this proposal.

(b) Data Submission Criteria for the Improvement Activities Performance Category

We refer readers to § 414.1360 for data submission criteria for the improvement activities performance category. In the CY 2022 PFS final rule (86 FR 65462), we finalized revisions to the data submission criteria at § 414.1360(a)(2) to allow subgroups to perform and attest to their improvement activities separately and to apply the 50 percent threshold within their subgroup. We inadvertently overlooked codifying subgroups in the regulation text at § 414.1360(a). The existing regulation text at § 414.1360(a) refers to data submission criteria in the improvement activities performance category for only MIPS eligible clinicians and groups. As described above, we are proposing to adopt this change retroactively pursuant to section 1871(e)(1)(A)(ii). We believe that the failure to apply the proposed change retroactively would be contrary to the public interest because it would create ambiguity in the data submission requirements established in § 414.1360(a)(2) regarding the reporting of improvement activities by subgroups. Therefore, we are proposing to revise § 414.1360(a) to state that for purposes of the transition year of MIPS and future years, MIPS eligible clinicians, groups, or subgroups must submit data on MIPS improvement activities in one of the following manners described at § 414.1360(a)(1) through (a)(1)(i).

We are requesting comments on this proposal.

e. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning in performance year 2021, which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation. We also established that ACOs will be required to report quality data for purposes of the Shared Savings Program via the APP (85 FR 84722).

Under policies finalized under the CY 2023 PFS (87 FR 69858), to meet the quality performance standard under the Shared Savings Program through the 2024 performance year, we stated that ACOs must report the ten CMS Web Interface measures or the three eCQMs/MIPS CQMS and the CAHPS for MIPS survey. Beginning in the 2025 performance year and subsequent performance years, ACOs must report the three eCQMS/MIPS CQMs and the CAHPS for MIPS survey (87 FR 69858 through 69859).

(2) Proposal for the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program

As discussed in section III.F.2.b.(2) of this proposed rule, we are proposing to establish the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) collection type in the APP measure set. The Medicare CQM collection type would be available to only ACOs participating in the Shared Savings Program. ACOs in the Shared Savings Program would have the option to report the Medicare CQM under the APP on only their attributed Medicare fee-for-service beneficiaries who meet the definition of a ''beneficiary eligible for Medicare CQM(s)'' as proposed in section III.F.2.b.(2) of this proposed rule, instead of their all payer/all patient population, beginning with the 2024 performance year. The Medicare CQM would also serve as another collection type in addition to the existing eCQM/MIPS CQM option, which is an all payer/all patient collection type under the APP.

In the CY 2023 PFS final rule, we stated that we will monitor the impact of policies such as the sunsetting of the CMS Web Interface in the 2024 performance year and the requirement to report all payer/all patient eCQMs/MIPS CQMs beginning in the 2025 performance year (87 FR 69833). We also stated that we may revisit these and related issues in future rulemaking based on lessons learned as we gain more experience with ACOs reporting eCQMs/MIPS CQMs (87 FR 69833). As discussed in section III.F.2.b.(2) of this proposed rule, we are committed to supporting ACOs in the transition to all payer/all patient eCQMs/MIPS CQMs and in the transition to digital quality measurement reporting. We encourage readers to review additional background on our proposal to include the Medicare CQM collection type in the APP measure set discussed at section III.F.2.b.(2) of this proposed rule.

f. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that

the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, and 87 FR respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In this proposed rule, we are proposing to:

- Amend the definition of the term ''collection type'' to include the Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs).
- Amend (through technical modifications) the data submission criteria for MIPS quality measures and establish the data submission criteria for Medicare CQMs.
- Require administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey in the Spanish translation.
- Maintain the data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/2028 MIPS payment year, and increase the data completeness criteria threshold to at least 80 percent for the CY 2027 performance period/2029 MIPS payment year.
- Establish data completeness criteria for Medicare CQMs.
- Modify the MIPS quality measure set as described in Appendix 1 of this proposed rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) Definition of Collection Type

With the proposed establishment of a new collection type, the Medicare Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare CQMs) specific to the APM Performance Pathway (APP) as described in section III.G.2. of this proposed rule, we are proposing to amend the definition of the term ''collection type'' to include Medicare CQMs in order account for the new collection type available only to Medicare Shared Savings Program ACOs meeting the reporting requirements of the APP. Specifically, starting with the CY 2024 performance period, we are proposing to amend the definition of the term ''collection type'' in § 414.1305 to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs). The Medicare CQMs collection type would serve as a transition collection type under the APP and be available as determined by CMS.

We seek public comment on the proposal to amend the definition of the term collection type to include the Medicare CQMs as an available collection type in MIPS.

(c) Quality Data Submission Criteria

(i) Data Submission Criteria for Quality Measures

In this proposed rule, we are proposing technical amendments to data submission criteria for MIPS quality measures and proposing to establish data submission criteria for Medicare CQMs. The participants in MIPS have expanded from MIPS eligible clinicians and groups to virtual groups starting with the CY 2018 performance period (82 FR 53593 through 53617), APM Entities starting with the CY 2021 performance period (85 FR 84860), and subgroups starting with the CY 2023 performance period (86 FR 65392 through 65394). In order to account for the expansion of participants in MIPS and the applicability of data submission criteria for MIPS quality measures, we are proposing technical amendments. We are proposing technical amendments to recognize that a virtual group, subgroup, and APM Entity are able to meet the data submission requirements pertaining to the quality performance category at § 414.1325(a)(1), (c), and (d). Also, we are proposing technical amendments to recognize that a virtual group and an APM Entity are able to meet the data submission requirements established at § 414.1335(a)(1)(i) and (ii) for the data submission criteria pertaining to Medicare Part B claims measures, MIPS CQMs, eCQMs, and QCDR measures. Additionally, in § 414.1335(a)(1)(ii), we are proposing to modify references of MIPS eligible clinicians and groups, to refer to such clinicians and groups in the singular to ensure that § 414.1335 uniformly references the various types of MIPS participants in the singular. We are making a grammatical correction to § 414.1335(a)(1)(i) to ensure subject-verb agreement. We note that the technical amendments in § 414.1335(a)(1)(i) and (ii) are not applicable to subgroups because MIPS subgroup participation is part of the MVP framework, which has separate data submission criteria specified in § 414.1365.

We are proposing technical amendments to the data submission criteria for the CAHPS for MIPS Survey measure, which would identify the CAHPS for MIPS Survey as a measure in § 414.1335(a)(3). The current rule does not reference the CAHPS for MIPS Survey as a measure, which is erroneous. Also, we are proposing a revision to § 414.1335(a)(3) to recognize that a virtual group, subgroup, and APM Entity are able to administer the CAHPS for MIPS Survey in § 414.1335(a)(3)(i).

Additionally, we are proposing amendments to the data submission criteria for quality performance category at § 414.1325(a)(1)(i) and (ii) in order to clarify that the data submission of MIPS quality measures specific to eCQMs must be submitted utilizing certified electronic health record technology (CEHRT). Section 1848(q)(5)(B)(ii) of the Act provides that under the methodology for assessing the total performance of each MIPS eligible clinician, the Secretary shall: (1) Encourage MIPS eligible clinicians to report on applicable measures under the quality performance category through the use of CEHRT and QCDRs; and (2) For a performance period for a year, for which a MIPS eligible clinician reports applicable measures under the quality performance category through the use of CEHRT, treat the MIPS eligible clinician as satisfying the CQMs reporting requirement under section 1848(o)(2)(A)(iii) of the Act for such year. To encourage the use of CEHRT for quality improvement and reporting on measures under the quality performance category, we established a scoring incentive for MIPS eligible clinicians who use their CEHRT systems to capture and report quality information, specifically the end-to-end electronic reporting bonus points (81 FR 77294

through 77297). We sunset the end-to-end electronic reporting bonus points starting with the CY 2022 performance period (CY 2021 performance period/2023 MIPS payment year was the last performance period in which the end-to-end electronic reporting bonus points were available (85 FR 84907 through 84908)).

With the framework for transforming MIPS through MVPs, we noted in the CY 2021 PFS final rule that we will find ways to incorporate digital measures without needing to incentivize end-to-end electronic reporting with bonus points (85 FR 84907 through 84908). In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged interested parties to consider electronically specifying their quality measures as eCQMs, to encourage MIPS eligible clinicians, groups, and virtual groups to move towards the utilization of electronic reporting. As noted in the CY 2019 PFS final rule (83 FR 59851), bonus points were created as transition policies which were not meant to continue through the duration of the program. Since the inception of MIPS, our intention has been to encourage the utilization of CEHRT, which encompasses the requirement of CEHRT pertaining to eCQM data submission.

With the sunset of the end-to-end electronic reporting bonus points, there is ambiguity regarding the requirement of utilizing CEHRT for the data submission of eCQMs. While the sunsetting of the end-to-end electronic reporting bonus points was merely to eliminate such bonus points, our intention was to continue the requirement of utilizing CEHRT for eCQM data submission. However, with the sunset of the end-to-end electronic reporting bonus points, there is an inadvertent absence in policy that would continue the requirement of utilizing CEHRT for eCQM data submission. As a result of such inadvertent absence of policy establishing the overarching CEHRT requirements for eCQM data submission for purposes of the quality performance category (aside from the CEHRT requirements under the end-to-end electronic reporting bonus point criteria), we are rectifying the issue by establishing the requirement to utilize CEHRT for the data submission of eCQMs. We are proposing to establish the quality performance category data submission criteria for eCQMs that requires the utilization of CEHRT in § 414.1335(a)(1). Specifically, in § 414.1335(a)(1)(i)(A) and (ii)(A), we are proposing that the data submission criteria for eCQMs requires the utilization of CEHRT, as defined in § 414.1305. Furthermore, we are proposing to amend the definition of CEHRT in § 414.1305(2)(ii) by broadening the applicability of the health IT certification criteria identified in 42 CFR 170.315 that are necessary to report objectives and measures specified under MIPS (would no longer be limited to the Promoting Interoperability performance category). As a result of this proposal, the health IT certification criteria identified in § 414.1305(2)(ii) would be applicable, where necessary, for any MIPS performance category, including the criteria that support eCQMs identified in § 414.1305(2)(ii)(B).

We note that the proposal pertaining to the data submission criteria for eCQMs requiring the utilization of CEHRT would not require third party intermediaries that report eCQMs on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to obtain certification. Currently, third party intermediaries may facilitate reporting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for an eCQM while not having been certified to the certification criteria at 45 CFR 170.315(c)(1) through (3). However, if a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity is relying on a third party intermediary for elements of the required certification capabilities for the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to meet the CEHRT definition applicable for their participation, then the third party intermediary would need to provide the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity with a certified Health IT Module for the needed capability or capabilities.

We note that the definition of CEHRT in § 414.1305 references several certification criteria in the ONC Health IT Certification Program for clinical quality measurement, including: ''Clinical quality measures (CQMs)—record and export'' (45 CFR 170.315(c)(1)), as part of the 2015 Base EHR definition in 45 CFR 170.102; ''Clinical quality measures (CQMs)—import and calculate'' (45 CFR 170.315(c)(2)); ''Clinical quality measures (CQMs)—report'' (45 CFR 170.315(c)(3)); and, optionally, ''Clinical quality measures (CQMs)—filter'' (45 CFR 170.315(c)(4)). Under this proposal, at a minimum, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity would need to utilize technology certified to the criteria at 45 CFR 170.315(c)(1) through (3) to report on eCQMs. We reiterate that certified Health IT Modules meeting these criteria are not required to be provided by the same health IT developer; a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity may use Health IT Modules to meet the certification requirements provided by more than one developer. For example, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could use certified health IT meeting the criteria in 45 CFR 170.315(c)(1) and (c)(2) provided as part of their EHR system while a third party intermediary that supports reporting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity could supply a Health IT Module that meets the criterion in 45 CFR 170.315(c)(3) to generate a measure report and thus, enable a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to meet the requirement to use CEHRT for eCQMs.

Lastly, we are proposing to establish data submission criteria for the Medicare CQM collection type (as proposed under the APP in section III.G.2. of this proposed rule) in § 414.1335(a)(4). Specifically, in § 414.1335(a)(4)(i), we are proposing that the data submission criteria pertaining to Medicare CQMs would be met by, a MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

We seek public comment on the proposals regarding the technical amendments that pertain to the data submission criteria for MIPS quality measures and the establishment of data submission criteria for Medicare CQMs.

(ii) Data Submission Criteria for the CAHPS for MIPS Survey Measure

The CAHPS for MIPS Survey measures patients' experience of care within a group, virtual group, subgroup, and APM Entity, including Shared Savings Program ACOs. The survey measures ten dimensions of patient experience of care, known as summary survey measures, for which patients may be the best, if not only source of information. The CAHPS for MIPS Survey is optional for all groups, virtual groups, subgroups, and APM Entities of 2 or more eligible clinicians reporting via traditional MIPS or MIPS Value Pathways (MVPs), and is required for Shared Savings Program ACOs reporting via the APM Performance Pathway (APP).

(A) Require the Administration of the CAHPS for MIPS Survey in the Spanish Translation

We have created official translations of the CAHPS for MIPS Survey in 7 languages, including Spanish, Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese, in addition to the required administration of English survey. However, use of these translations is generally voluntary, with the exception of the requirement to administer the Spanish translation of the CAHPS for MIPS Survey for patients residing in Puerto Rico. Groups, virtual groups, subgroups, and APM Entities that elect CAHPS for MIPS Survey must contract with a CMS-approved survey vendor to administer the CAHPS for MIPS Survey, and must request survey translations for the vendor to administer the CAHPS for MIPS Survey in an optional language. Generally, the CAHPS for MIPS Survey translations are an additional cost to the groups, virtual group, subgroup, and APM Entities.

Our analysis of historic CAHPS data indicates that the use of survey translations has not been widespread and there is unmet need for access to surveys in the 7 available translations. The analysis of survey translation use by groups and Shared Savings Program ACOs fielding the CY 2021 performance period CAHPS for MIPS Survey indicates that 406 out of 559 organizations have about one percent to 9 percent respondents reporting they speak a language other than English at home, and 141 out of 559 organizations have 10 percent or more respondents reporting they speak a language other than English at home. Among these 141 organizations with 10 percent or more respondents reporting they speak a language other than English at home, 114 organizations have all of their survey responses in English. These data highlight a potential gap in the need for and access to a CAHPS for MIPS Survey translation within at least 20 percent (114 out of 559 organizations) of the groups and Shared Savings Program ACOs administering the 2021 CAHPS for MIPS Survey. For the CAHPS for MIPS Survey, the most common non-English language spoken at home by patients is Spanish. We analyzed data from the U.S. Census Bureau, specifically from the 2021 American Community Survey, and found that Spanish is spoken by 61 percent of those who speak a language other than English at home.[311] Among those age 65 and older who speak a language other than English at home, 49 percent speak Spanish. Requiring groups, virtual groups, subgroups, and APM Entities to administer the CAHPS for MIPS Survey in English and Spanish would therefore address much of the unmet need. The requirement would indirectly require vendors to offer the administration of the Spanish translation of the CAHPS for MIPS Survey, and would increase costs to groups, virtual groups, subgroups, and APM Entities.

We propose to require the administration of the CAHPS for MIPS Survey in the Spanish translation; more specifically, we propose to require groups, virtual groups, subgroups, and APM Entities to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, would administer the Spanish translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. Also, we are recommending that groups, virtual groups, subgroups, and APM Entities administer the survey in the other available translations (Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese) based on the language preferences of their patients. The proposal and recommendation would make the survey more accessible to survey respondents who can only respond in Spanish or another available translation, and provide an opportunity to better understand their experiences of care and any disparities in care.

Furthermore, the requirement of the administration of the Spanish translation and the recommendation of utilizing the other translations of the CAHPS for MIPS Survey align with CMS's effort to provide culturally and linguistically appropriate services (CLAS), which are intended to advance health equity, improve quality, and help eliminate health care disparities.[312] Other CMS-administered CAHPS Surveys, such as the Medicare Advantage and Prescription Drug Plan CAHPS, require the administration of Spanish translation survey. For the fiscal year (FY) 2024 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule, the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program is proposing to require hospitals to collect information about the language that the patient speaks while in the hospital (whether English, Spanish, or another language), and that the official Spanish translation of the Hospital CAHPS Survey be administered to all patients who prefer Spanish (88 FR 27114).

We seek public comment on the proposal to require the administration of CAHPS for MIPS Survey in the Spanish translation. In addition, we are interested in comments from organizations that administer the CAHPS for MIPS Survey on whether they consider contracting with vendors to administer the survey in one or more of the available survey translations based on the language preferences of patients. If so, we are also interested in learning about the factors that more or less likely affect the administration of survey translations where there is need for one or more of the available translations. These comments may inform future rulemaking.

(d) Data Completeness Criteria

(i) Data Completeness Criteria for Quality Measures, Excluding the Medicare CQMs

As described in the CY 2017 Quality Payment Program proposed rule (81 FR 28188 and 28189), to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance, we established a data completeness requirement. Section 1848(q)(5)(H) of the Act provides that analysis of the quality performance category may include quality measure data from other payers, specifically, data submitted by MIPS eligible clinicians with respect to items and services furnished to individuals who are not individuals entitled to benefits under Part A or enrolled under Part B of Medicare. In the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2020 PFS final rule, we also noted that we would increase the data completeness criteria threshold over time (81 FR 77121, 82 FR 53632, and 84 FR 62951). For the CY 2017 performance period/2019 MIPS payment year (first year of the implementation of MIPS), CMS established the data completeness criteria threshold to reflect a threshold of at least 50 percent (81 FR 77125). We increased the data completeness criteria threshold from at least 50 percent to at least 60 percent for the CY 2018 performance period/2020 MIPS payment year (81 FR 77125 and 82 FR 53633) and maintained a threshold of at

[311] U.S. Census Bureau, 2021 American Community Survey, S1603: Characteristics of People by Language Spoken at Home, 2021 American Community Survey 5-Year Estimate Subject Tables. Available at *https://data.census.gov/table?q=S1603&tid=ACSST5Y2021.S1603.*

[312] Centers for Medicare & Medicaid Services. Achieving Health Equity. Available at *https://www.cms.gov/Outreach-and-Education/MLN/WBT/MLN1857916-OMH-AHE/OMHAHE/ahe/lesson01/09/index.html.*

least 60 percent for the CY 2019 performance period/2021 MIPS payment year (82 FR 53633 and 53634). For the CY 2020 performance period/2022 MIPS payment year, we increased the data completeness criteria threshold from at least 60 percent to at least 70 percent (84 FR 62952). We maintained data completeness criteria threshold of at least 70 percent for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years (86 FR 65435 through 65438). For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, we increased the data completeness criteria threshold from at least 70 percent to at least 75 percent (87 FR 70049 through 70052). We continue to believe that it is important to incrementally increase the data completeness criteria threshold as MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities gain experience with MIPS.

The incorporation of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, and 87 FR 70049). We have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients (82 FR 53632, 86 FR 65436, and 87 FR 70049). The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. A data completeness criteria threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program (82 FR 53632, 86 FR 65436, and 87 FR 70049).

We previously noted concerns raised by interested parties regarding the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS (81 FR 77121, 82 FR 53632, 84 FR 62951, and 87 FR 70049). We want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period,[313] it is feasible for eligible clinicians and groups to achieve a higher data completeness criteria threshold without jeopardizing their ability to successfully participate and perform in MIPS.

As MIPS eligible clinicians, groups, and virtual groups have gained experience participating in MIPS, particularly meeting the data completeness criteria threshold over the last 7 years (from CY 2017 performance period to CY 2023 performance period), such experience has prepared MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entity to meet incremental increases in the data completeness criteria threshold. We have maintained a data completeness criteria threshold of at least 70 percent for four years from the CY 2020 performance period to the CY 2023 performance period and as a result, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities had 4 years of a maintained data completeness criteria threshold of at least 70 percent before transitioning to an increased data completeness criteria threshold of at least 75 percent for a 2-year timeframe (CY 2024 and CY 2025 performance periods) with more than 12 months to prepare for an increased data completeness criteria threshold of at least 75 percent before such threshold becomes effective for the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

As we assessed the timeframe for increasing the data completeness criteria threshold, we determined that maintaining the data completeness criteria threshold of at least 75 percent for a total of 3 years would provide sufficient time for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to transition to another increase in the data completeness criteria threshold. For the CY 2026 performance period/2028 MIPS payment year, we are proposing to maintain the data completeness criteria threshold of at least 75 percent. This would provide MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities with sufficient time to prepare for an incrementally increase in the data completeness criteria threshold starting with the CY 2027 performance period/2029 MIPS payment year. Therefore, MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities could continue transitioning to an incrementally increased data completeness criteria threshold of at least 75 percent to at least 80 percent. In establishing data completeness criteria thresholds in advance of an applicable performance period, it is advantageous to delineate the expectations for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, so they can adequately prepare for a transition to higher data completeness criteria threshold, particularly the increase in data completeness criteria threshold to at least 80 percent. Thus, we are proposing to increase the data completeness criteria threshold from 75 percent to 80 percent for the CY 2027 performance period/2029 MIPS payment year.

The use of electronic health records (EHRs) and eCQMs can reduce burden associated with meeting higher data completeness standards as the collection of eCQM data within the EHR can allow eligible clinicians to report on 100 percent of the eligible population with data in the EHR for a measure. We continue to encourage individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, including small and rural practices, to explore EHR adoption and the reporting of eCQMs to reduce burden and technical challenges to ensure data accuracy as we seek to increase the data completeness criteria threshold. Individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities that continue to utilize other means of data collection for MIPS CQMs, including the collection of MIPS CQM data reported by registries and/or QCDRs, would need have the logic code of their EHRs to be updated to account for the increased data completeness criteria threshold. Increasing the data completeness criteria threshold would not pose a substantial burden to MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, unless they are manually extracting and reporting quality data. However, increasing the data completeness criteria threshold provides for the more accurate assessment of performance.

For the aforementioned reasons, it is important to incrementally increase the data completeness criteria threshold. In this proposed rule, we are proposing to maintain the data completeness threshold for an additional year before incrementally increasing the data completeness criteria threshold. Specifically, in § 414.1340(a), we are proposing the following data completeness criteria thresholds pertaining to QCDR measures, MIPS CQMs, and eCQMs:

- At paragraph (a)(4), for the CY 2026 performance period/2028 MIPS

[313] As described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76.

payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

- At paragraph (a)(5), for the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

Similarly, in § 414.1340(b), respectively, we are proposing the following data completeness criteria thresholds pertaining to Medicare Part B claims measures:

- At paragraph (b)(4), for the CY 2026 performance period/2028 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.
- At paragraph (b)(5), for the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.

Also, for the data completeness criteria pertaining to the quality performance category, we are proposing technical amendments to recognize that a virtual group, subgroup, and APM Entity must meet the data completeness criteria requirements established at § 414.1340(a), (b), and formerly paragraph (d), new paragraph (e) due to the proposal to establish the data completeness criteria for the new collection type, Medicare CQM, in § 414.1340(d) as discussed in the following section, IV.A.4.f.(1)(d)(ii), of this proposed rule.

We seek public comment on these proposals.

(ii) Data Completeness Criteria for the Medicare CQMs

As we propose to establish a new collection type, the Medicare CQMs specific to the APM Performance Pathway (APP) as described in section III.G.2. of this proposed rule, we are also proposing to establish the data completeness criteria thresholds for the Medicare CQMs. Specifically, in § 414.1340(d), respectively, we are proposing the following data completeness criteria thresholds pertaining to Medicare CQMs:

- At paragraph (d)(1), for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, and 2028 MIPS payment years, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.
- At paragraph (d)(2), for the CY 2027 performance period/2029 MIPS payment year, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 80 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.

We are proposing to establish the aforementioned data completeness criteria thresholds for the Medicare CQMs collection type in advance of the applicable performance periods. We recognize that it is advantageous to delineate the expectations for ACOs as they prepare to meet the quality reporting requirements for the Medicare CQMs collection type under the APP. We will assess the availability of the Medicare CQMs as a collection type under the APP during the initial years of implementation and determine the timeframe to sunset the Medicare CQM as a collection type in future rulemaking.

(e) Selection of MIPS Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding to the list, as appropriate, new measures; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2023 PFS final rule (87 FR 70250 through 70633), CY 2022 PFS final rule (86 FR 65687 through 65968); CY 2021 PFS final rule (85 FR 85045 through 85377); CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). We are proposing changes to the MIPS quality measure set, as described in Appendix 1 of this proposed rule, include the following: the addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the CY 2024 performance period, we are proposing a measure set of 200 MIPS quality measures in the inventory.

The new MIPS quality measures that we are proposing to include in MIPS for the CY 2024 performance period and future years can be found in Table Group A of Appendix 1 of this proposed rule. For the CY 2024 performance period, we are proposed 14 new MIPS quality measures, which includes one composite measure; and 7 high priority measures, of which 4 are also patient-reported outcome measures.

In addition to the establishment of new individual MIPS quality measures, we develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. We are proposing modifications to existing specialty sets and new specialty sets as described in Table Group B of Appendix 1 of this proposed rule. Specialty sets may include: new measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 3, 2023, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 8 of MIPS under the Quality Payment

Program.[314] These recommendations were based on the MIPS quality measures finalized in the CY 2022 PFS final rule and the 2022 Measures Under Consideration List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with were proposed in this proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as described in Tables Group A and Group B of Appendix 1 of this proposed rule, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of quality measures and rationales for measure removal. We have previously specified certain criteria that will be used when we are considering the removal of a measure (81 FR 77136 and 77137; 83 FR 59763 through 59765; 84 FR 62957 through 62959). For the CY 2024 performance period, we are proposing to remove 12 MIPS quality measures and partially remove 3 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs. We refer readers to Table Group DD of Appendix 1 of this proposed rule for further information regarding the proposals to retain such measures for retention for use in relevant MVPs. Of the 12 MIPS quality measures proposed for removal, the following pertains to such measures: 2 MIPS quality measures are duplicative to a proposed new MIPS quality measure; 3 quality measures are duplicative of current measures; 5 MIPS quality measures that are under the topped-out lifecycle; one measure is extremely topped out; and one MIPS quality measure is constructed in a manner that makes it difficult to attribute the quality action to the clinician, which creates burden. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (*see,* for example, 83 FR 59763 through 59765). The proposal to remove the quality measures described in Table Group C of the this proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the quality measures to determine whether they meet our removal criteria.

Also, we are proposing substantive changes to several MIPS quality measures, which can be found in Table Group D of Appendix 1 of this proposed rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 through 65442). We are proposing substantive changes to 59 MIPS quality measures, which includes 3 MIPS quality measures proposed to be retained for utilization under MVPs (we refer readers to Table Group DD of Appendix 1 of this proposed rule for such measures that are proposed for retention for use in relevant MVPs). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive.

Lastly, we are proposing substantive changes to the CMS Web Interface measures that are available as a collection type and submission type for the Medicare Shared Savings Program ACOs meeting reporting requirements under the APP. The substantive changes to the CMS Web Interface measures can be found in Table Group E of Appendix 1 of this proposed rule.

We seek public comment on the proposals to modify the quality performance category measure set, a measure set of 200 MIPS quality measures in the inventory for the CY 2024 performance period, which includes the following:

- Implementation of 14 new MIPS quality measures: one composite measure; and 7 high priority measures, of which 4 are also patient-reported outcome measures;
- Removal of 12 MIPS quality measures: 2 quality MIPS measure are duplicative to a proposed new quality measure; 3 MIPS quality measures are duplicative to current quality measures; 5 MIPS quality measures are under the topped-out lifecycle; one MIPS quality measure is extremely topped out; and one MIPS quality measure is constructed in a manner that makes it difficult to attribute the quality action to the clinician, which creates burden;
- Partial removal of 3 MIPS quality measures: 3 MIPS quality measures removed from traditional MIPS and retained for use in MVPs; and
- Substantive changes to 59 MIPS quality measures.

(2) Cost Performance Category

Section 1848(q)(2)(A) of the Act includes resource use as a performance category under the MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the cost performance category.

In this proposed rule, we are proposing to add five new episode-based measures to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. These five measures are: Depression, Emergency Medicine, Heart Failure, Low Back Pain, and Psychoses and Related Conditions. We are proposing that MIPS eligible clinicians must meet or exceed a minimum of 20 cases for each of these measures to be assessed on such measure, and we are seeking comments on our interpretation of the language on the case minima codified at § 414.1350(c). We are also proposing to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. Finally, we are proposing to add the five new episode-based measures and remove the Simple Pneumonia with Hospitalization episode-based measure from the operational list of care episode and patient condition groups and codes.

For a description of the statutory basis for and existing policies pertaining to the cost performance category, we refer readers to § 414.1350 and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), and CY 2023 PFS final rule (87 FR 70055 through 70057).

(a) Addition of Episode-Based Measures

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance

[314] Message to the Quality Payment Program listserv on January 3, 2023, entitled: ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2024 Performance Year of the Merit-based Incentive Payment System (MIPS).''

category. There are currently 25 cost measures in the cost performance category for the CY 2023 performance period/2025 MIPS payment year, comprising of 23 episode-based measures covering a range of conditions and procedures and two population-based measures. We worked with the measure development contractor to identify the proposed five new episode-based measures for development through empirical analyses and public comment. These proposed measures cover clinical topics and MIPS eligible clinicians currently with limited or no applicable cost measures. As such, these proposed measures would help fill gaps in the cost performance category's measure set. In addition, these proposed measures would support the transition from traditional MIPS to MIPS Value Pathways (MVPs) by allowing for new MVPs to be created and enhancing existing MVPs. Further, the addition of these proposed measures would address interested parties' feedback about the need for more clinically refined episode-based measures in the cost performance category. This proposal would also increase the cost coverage of care episode and patient conditions groups, moving closer towards the statutory goal of covering 50 percent of expenditures under Medicare Parts A and B, as specified under section 1848(r)(2)(i)(I) of the Act.

At a high level, episode-based measures represent the cost to Medicare and beneficiaries for the items and services furnished during an episode. They aim to compare MIPS eligible clinicians on the basis of the cost of care that is clinically related to their treatment and management of a patient and provided during the episode's timeframe. Specifically, for such measures, we define and measure the cost of care for the episode based on the allowed amounts on Medicare claims, which include both Medicare trust fund payments and any applicable beneficiary deductible and coinsurance amounts. The cost of care for these measures includes amounts paid under Medicare Parts A and B, and, on a case-by-case basis, Medicare Part D that have been standardized to remove price variation from non-clinical factors. The Parts A and B payment standardization methodology and the Part D payment standardization methodology are available at *https://resdac.org/articles/cms-price-payment-standardization-overview.* Information about how the Part D standardization methodology incorporates rebates into standardized amounts is available at *https://www.cms.gov/files/document/2023-part-d-rebate-methodology.pdf.* We refer the readers to section IV.A.4.f.(2)(a)(iii) of this proposed rule for more information on the five episode-based measures we are proposing.

In this proposed rule, we provide detail about the new measures that we are proposing to include in the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. In section IV.A.4.f.(2)(a)(ii) of this proposed rule, we summarize the timeline for development of these proposed measures, including engagement activities undertaken by the measure development contractor. In section IV.A.4.f.(2)(a)(iii) of this proposed rule, we summarize the proposed new measures that would be included in the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. For the proposed Emergency Medicine episode-based measure, we provide detail about the measure's construction, which evaluates a MIPS eligible clinician's or clinician group's risk-adjusted cost of care to Medicare for patients who receive treatment in the Emergency Department (ED) setting. In section IV.A.4.f.(2)(b) of this proposed rule, we discuss our proposal that MIPS eligible clinicians must meet or exceed a minimum of 20 cases for each of these proposed measures to be assessed on such measure and request comments on our interpretation of case minima regulatory language.

(ii) Overview of Measure Development Process for New Episode-Based Measures

In this section, we describe the development process for the five proposed episode-based measures.

Development of episode-based measures for the cost performance category must comply with the statutorily required processes set forth in section 1848(r) of the Act. We note that the measure developer uses a ''wave'' approach to indicate cycles of measure development where clinical expert panels convene to select episode groups to develop into cost measures and to provide input on the measures' specifications. All five of the proposed measures have been developed with extensive engagement from interested parties, including clinicians, persons with lived experience, and the general public. The term ''persons with lived experience,'' as used in this section IV.A.4.f.(2) of this proposed rule, refers to persons and family of persons who have experienced these conditions or diseases. Our approach to engagement is outlined in the CY 2018 Quality Payment Program final rule (82 FR 53644 through 53645), the CY 2019 PFS final rule (83 FR 59767 through 59769), and the CY 2022 PFS proposed rule (86 FR 39396 through 39397). These processes have been refined over time to incorporate feedback from interested parties, such as to extend the development timeline from 12 months in Wave 2 to 18 months in Waves 3 and 4, and to integrate bidirectional conversations between persons with lived experience and clinical experts.

Four of these measures began development in 2020 in Wave 4 of development, and one of these measures has been in development and refinement since 2018 (as part of Wave 2 of measure development). Specifically, the Depression, Emergency Medicine, Heart Failure, and Low Back Pain episode-based measures were developed in the Wave 4 cycle of measure development through an 18-month process. As a first step, the measure development contractor held a public comment period from December 2020 through February 2021 to gather feedback on which clinical areas to prioritize for development. During the public comment period, the measure developer received 36 comments on the candidate episode groups for development in Wave 4. This feedback, in conjunction with empirical testing by the measure development contractor, was used to inform the decision to develop these specific clinical areas—depression, emergency medicine, heart failure, and low back pain—into episode-based measures. The summary of the public comments is available in this document *https://www.cms.gov/files/document/wave-4-public-comment-summary.pdf.*

Following our decision to develop measures for depression, emergency medicine, heart failure, and low back pain, the measure development contractor convened four clinician expert panels, comprised of a total of 73 members, affiliated with 63 organizations and specialty societies. Each panel also incorporated the perspective of persons with lived experience following a new approach where their input is collected via structured focus groups, interviews or surveys, and then summarized and presented to the clinical expert panels.

Then, the measure development contractor held a national field testing period from January 14, 2022 to March 25, 2022. During this field testing period, MIPS eligible clinicians and clinician groups meeting a minimum threshold of episodes for each measure could review field test reports and an episode-level file with detailed

information to understand the types of services that comprise a large or small share of their episode costs. Supplemental materials, such as testing information on measures, a Frequently Asked Questions document, and mock field test reports were posted publicly for interested parties' review. The measure development contractor gathered all feedback via a survey and a summary of this feedback from the field testing period is available at *https://www.cms.gov/files/document/2022-field-testing-feedback-summary-report.pdf*.

The measure development contractor also has a standing technical expert panel (TEP), composed of 20 members from different clinical areas, academia, health care and hospital administration, and persons with lived experience, which provides overarching input on cross-measure topics, such as testing approaches and methodology. For example, the TEP discussed challenges in developing chronic condition episode-based measures and ways that the framework can address those challenges, provided feedback on the attribution rules (that is, the algorithms and the types of codes used in each algorithm) that would demonstrate a relationship between a clinician group and a patient with a chronic condition(s), and discussed service assignment, risk adjustment, and exclusions. This input helped inform the specifications for the chronic condition episode-based measure framework, which serves as the framework for three of the chronic condition episode-based measures (that is, Depression, Heart Failure, and Low Back Pain episode-based measures) developed in Wave 4 and being proposed in this proposed rule.

Separately from the other four proposed measures, the Psychoses and Related Conditions measure originally had begun development in 2018 as part of Wave 2, alongside 10 other episode-based measures. However, this measure has not yet been implemented in the cost performance category. During the 2018 through 2019 measure development cycle, a convened clinical expert workgroup met four times to provide detailed input on the measure and the measure was field tested as part of the field testing period in 2018. The summaries of the workgroup webinars as well as the comments received on the original version of the measure during field testing are available on the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We included the Psychoses and Related Conditions measure in the ''2018 Measures Under Consideration List'' (*https://www.cms.gov/files/document/2018rmuc-listclearancerpt.pdf*) and the Measure Application Partnership (MAP) reviewed the measure during the 2018–2019 review cycle. In December 2018, the MAP Clinician Workgroup provided the Psychoses and Related Conditions episode-based measure a preliminary recommendation of ''Conditional support for rulemaking,'' on the condition of endorsement by a consensus-based entity (CBE). In January 2019, the MAP Coordinating Committee overturned the MAP Clinician Workgroup's recommendation and voted to replace it with a recommendation of ''Do not support for rulemaking.'' The MAP Coordinating Committee's concerns with the Psychoses and Related Conditions measure related to: (1) the measure's attribution model and its potential to hold clinicians responsible for costs outside of their influence; (2) geographic variation in community resource availability; (3) effects of physical comorbidities on measure score; and (4) the potential to exacerbate access issues in mental health care. For more detail please refer to the final report at *http://www.qualityforum.org/Publications/2019/03/MAP_Clinicians_2019_Considerations_for_Implementing_Measures_Final_Report.aspx.*

In the CY 2020 PFS proposed rule (84 FR 40760), we responded to the MAP Coordinating Committee's concerns, as we believed that these concerns had already been addressed through the development and testing processes, and solicited comments as part of the request for information (RFI) on the potential use of the original draft version of the Psychoses and Related Conditions episode-based measure in the cost performance category in a future MIPS performance period.

The measure development contractor considered the MAP Coordinating Committee's comments and responses to the RFI that we received when refining the Psychoses and Related Conditions measure in 2021–2022. In October 2021, the measure developer reconvened the Psychoses and Related Conditions Clinical Expert Workgroup to consider measure refinements to address concerns, noting that the measure concept continued to be important as it would encourage value in mental health care. The details of these refinements are outlined in section IV.A.4.f.(2)(a)(iii) of this proposed rule. Then, the measure development contractor field tested the Psychoses and Related Conditions measure alongside the other four proposed new episode-based measures discussed previously in this section of the proposed rule. The feedback received during field testing was further discussed by the Psychoses and Related Conditions Clinical Expert Workgroup in April 2022.

More information about the measure development and interested parties engagement process for the five proposed episode-based measures for inclusion in the cost performance category is available in materials on the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.* Summaries of the public comment period and clinician expert workgroup meetings organized by the measure development contractor are also available on the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures*.

Similar to previous years, the measure development contractor has continued to engage clinicians and interested parties through the standing TEP, public comment periods, measure-specific Clinical Expert Workgroups, Person and Family Engagement opportunities, and national field testing, as well as conduct extensive education and outreach activities. For more information on the methods through which the measure development contractor gathered expert input during measure development and other interested parties engagement activities, please refer to the ''2023 Summary of Cost Measures'' document that is available at *https://www.cms.gov/files/document/2023-mips-summary-cost-measures.pdf.*

After these extensive measure development and refinement activities, we included the five proposed episode-based measures on our 2022 Measures Under Consideration (MUC) List (available for download at *https://mmshub.cms.gov/sites/default/files/2022-MUC-Lst.xlsx*) to be considered for potential use in MIPS. The MAP reviewed the measures during the 2022–2023 review cycle. This process involved reviews by the MAP Health Equity and MAP Rural Health Advisory Groups, as well as two public comment periods. In December 2022, the MAP Clinician Workgroup discussed the measures, taking into consideration the input from the MAP Health Equity and MAP Rural Health Advisory Groups and the public comments. The MAP Clinician Workgroup reached consensus to conditionally support all five episode-based measures for rulemaking, pending the endorsement of the

measures by a CBE. The MAP Clinician Workgroup's concerns related to the inclusion of Medicare Part D covered items and services in certain measures, potential unintended consequences of assessing costs related to mental health care, appropriateness of the attribution methodology, and request for additional detail on testing into adjusting for social determinants of health (for example, geographic location and socioeconomic status) and evidence of care stinting. In January 2023, the MAP Coordinating Committee upheld the MAP Clinician Workgroup's preliminary recommendation. More information about these recommendations is available in the 2022–2023 MAP Final Recommendations document at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&itemID=98102*.

We believe that the concerns raised regarding these proposed measures have been addressed during measure development and the MAP meetings. Additionally, some interested parties recognized the importance of these measures, specifically highlighting the importance of episode-based measures assessing mental health care. We agree with these interested parties. On these bases, we are proposing all five of these episode-based measures for inclusion in the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

(iii) New Episode-Based Measures Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In this section of this proposed rule, we discuss the five new episode-based measures, which we propose to add to the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

In conjunction with our measure development contractor, we developed these measures with consideration of the common standards that are described in the CY 2022 PFS final rule (86 FR 65455 through 65459) to ensure consistency across episode-based measures being developed. Specifically, the CY 2022 PFS final rule requires that any episode-based measure for the cost performance category include the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment. The five new episode-based measures we are proposing meet all requirements described in CY 2022 PFS final rule, including these features. We provide more information on the specific requirements for each of the proposed episode-based measures later in this section of the proposed rule.

Generally, for all episode-based measures, we exclude episodes where costs cannot be fairly compared to the costs for the whole cohort in the episode-based measure. These exclusions, like other features of each episode-based measure, are developed with extensive clinician and interested parties' engagement. We have specified exclusions for all five proposed episode-based measures, and discuss certain exclusions for the Psychoses and Related Conditions and the Emergency Medicine measure in further detail in this section of this proposed rule.

Generally, we also apply a risk adjustment model to all episode-based measures in the cost performance category. The model includes standard risk adjustors that are applied to all episode-based measures (for example, CMS Hierarchical Condition Category [HCC] variables, comorbidities, age brackets, disability status, ESRD status), and measure-specific risk adjustors (for example, patient transfers from another setting for the Emergency Medicine measure). We assess the risk adjustment model at the level of each stratification to ensure that only like patients are compared to each other. The risk adjustment model we use in development of the cost performance category's episode-based measures is described in greater detail in CY 2019 PFS final rule (83 FR 59767 through 59773). As mentioned previously in this section, all five proposed episode-based measures have been risk adjusted in accordance with this model.

More information on the episode-based measure development requirements, which were outlined so that external interested parties could develop measures in the future, are available in the Blueprint for the CMS Measures Management System (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*) and the Meaningful Measures Framework (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*).

The episode-based measures that we are proposing for CY 2024 performance period/2026 MIPS payment year and future performance periods are listed in the Table 43.

TABLE 43: Proposed Episode-Based Measures Beginning with CY 2024 Performance Period/CY 2026 MIPS Payment Year

Measure Name	Episode Type
Depression	Chronic condition
Emergency Medicine	Care Setting
Heart Failure	Chronic condition
Low Back Pain	Chronic condition
Psychoses and Related Conditions	Acute inpatient medical condition

The three chronic condition episode-based measures assess outpatient treatment and ongoing management of the following chronic conditions: depression, heart failure, and low back pain. The measure construction for these three proposed measures follows the approach described in the CY 2022 PFS final rule (86 FR 65445 through 65461), which also includes detailed discussion of the attribution methodology and examples of how episodes are attributed.

The attribution methodology that identifies a clinician-patient care relationship is slightly different at the clinician group and individual MIPS eligible clinician levels, to reflect that care provided at the clinician group and individual MIPS eligible clinician levels, respectively. At a high level, these proposed chronic condition episode-based measures attribute episodes to the clinician group that renders services that constitute a trigger event, which is identified by the occurrence of two claims billed in close proximity by the same clinician group.

Both claims must have a diagnosis code indicating the same chronic condition related to the specific episode-based measure. For example, for the Heart Failure measure, both claims of the trigger event must have a diagnosis indicating heart failure. The services that trigger an event for these chronic condition episode-based measures are identified first by Evaluation and Management (E/M) codes for outpatient services, and then by a second claim with either another E/M code for outpatient services or a condition-related Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) code (CPT/HCPCS) related to the treatment or management of the chronic condition. The trigger event opens a year-long attribution window from the date of the initial E/M outpatient service, during which the same clinician group could reasonably be considered responsible for managing the patient's chronic condition. If we see evidence that the relationship is ongoing, represented by another E/M or condition-related procedure code that we refer to as the reaffirming claim, then this window can be extended.

For individual MIPS Eligible clinicians, we would attribute episodes to each individual MIPS eligible clinician within an attributed clinician group that renders at least 30 percent of trigger or reaffirming codes on Part B Physician/Supplier claim lines during the episode, such as office visits or diagnostic services. We also apply conditions to ensure the MIPS eligible clinicians to whom the episode is attributed are reasonably responsible for the management of the patient's chronic condition. Specifically, the MIPS eligible clinician must have provided condition-related care to this patient prior to or on the episode start date.

Additionally, we use the provider-level prescription billing patterns to ensure that we are capturing the MIPS eligible clinicians directly involved in providing ongoing chronic care management, rather than clinicians who might have only refilled a patient's prescription once, as a courtesy to the patient. Specifically, for some measures (that is, Diabetes, Asthma/COPD episode-based measure that were finalized for use in the MIPS cost performance category for the CY 2022 PFS final rule (86 FR 64996), and Heart Failure episode-based measure that is being proposed in this rule.

The Psychoses and Related Conditions measure is an acute inpatient medical condition episode-based measure, which focuses on patients hospitalized for schizophrenia, delusional disorders, brief psychotic disorder, schizoaffective disorder, manic episode with psychotic symptoms, bipolar disorder with psychotic symptoms, major depressive disorder with psychotic symptoms, or unspecific psychosis. This acute inpatient medical condition was developed in accordance with the previously established framework for episode-based measures, which we described in detail in the CY 2019 PFS final rule (83 FR 59769 through 59771). We selected the Psychoses and Related Conditions measure for development because empirical analyses have identified psychoses-related hospitalizations are one of the most common inpatient stays, so it has a strong potential to be impactful on Medicare spending. This measure would also contribute to filling the current identified gap in the cost performance category's measurement of mental health care, as currently there are no episode-based or other cost measures assessing this clinical area.

As noted in the previous section of this proposed rule, the Psychoses and Related Conditions measure has been refined since the RFI in CY 2020 PFS proposed rule (84 FR 40760 through 40761) considering expert and other interested parties' input and to further address the MAP Coordinating Committee's previously expressed concerns in the 2018–2019 measure development cycle about the ability of inpatient clinicians to affect post-discharge care. In response to this input and these concerns, we implemented three refinements of this measure. First, we reduced the length of the episode window reduced from 90 to 45 days. This shortened episode window helps to ensure that MIPS eligible clinicians can reasonably be held accountable for post-discharge care, while still capturing readmissions and ED visits shortly after the trigger event, which persons with lived experience had noted as being important outcomes to identify and measure because these outcomes could be avoided with better discharge planning and follow-up care. Second, we refined this measure's specifications to account for specific scenarios where MIPS eligible clinicians have limited ability to influence a patient's care. Specifically, this measure now excludes episodes with involuntary holds at admission and episodes which are transfers to State hospitals. Third, we refined this measure's specifications to risk adjust for facility type to account for differences in payment policies between Inpatient Prospective Payment System (IPPS) and Inpatient Psychiatric Facility (IPF) hospitals. While we continue to believe that the original measure had accounted for concerns about the ability of inpatient clinicians to influence costs after discharge as described in the CY 2020 PFS proposed rule (84 FR 40760 through 40761), we also believe that these changes further refine the measure to meaningfully assess costs related to the role of clinicians caring for patients during mental health hospitalizations.

The Emergency Medicine measure assesses the cost of care clinically related to the treatment of a patient during an ED visit. The intent of this measure is to comprehensively assess all types of care in an ED, so the construction of the measure reflects the goal of capturing this broad scope of care. As such, this measure is characterized as a ''care setting'' episode type.

A CPT/HCPCS code indicating that a clinician has furnished care in the ED setting triggers the Emergency Medicine measure. The clinician billing the trigger code is attributed the episode. A clinician group is attributed by aggregating all episodes attributed to clinicians that bill to the clinician group. The trigger code also opens a 14-day episode window, during which the attributed clinician is responsible for costs.

The Emergency Medicine measure stratifies episodes based on the type of care the patient received during their ED visit and by disposition status. First, episodes are divided into 28 mutually exclusive groups called ED visit types that characterize the focus of care a patient received during their visit. These represent more granular, exhaustive patient populations defined by clinical criteria including the three-digit diagnosis codes available on a patient's ED visit claims, as well as a Medicare Severity Diagnosis Related Group (MS–DRG) of a subsequent inpatient stay if present. Given the goal of the Emergency Medicine measure to capture the broader universe of care provided in the emergency setting, dividing this measure's episodes into ED visit types is a technique to ensure clinical comparability. Examples of a few of the most frequent ED visit types associated with this Emergency Medicine measure are respiratory, gastrointestinal or liver, and kidney and urinary conditions. The 28 ED visit types are further stratified by whether (1) the ED visit resulted in subsequent observation care or inpatient admission or (2) the patient was discharged without subsequent observation care or inpatient admission. For example, ED visits for a stroke which end in

discharge are only compared with other ED visits for a stroke that also end in discharge.

The Emergency Medicine measure includes all Medicare Parts A and B services during the 14-day episode window, except for certain services determined to not be clinically relevant to the ED visit type. This reflects the intent of the measure and the broad clinician role in the ED setting. The ED visit type associated with the specific episode determines whether a service is clinically unrelated and therefore excluded from the episode. For example, if a patient visits the ED for ear, nose and throat (ENT) and eye disorders, any subsequent services for psychoses or behavioral and developmental disorders are excluded. However, if a patient visits the ED to receive care for an altered mental state, these subsequent services for psychoses or behavioral and developmental disorders are not excluded.

The Emergency Medicine measure risk adjusts costs just like all other episode-based measures. This measure uses the standard risk adjustment model described previously in this section. Also, as discussed, we assessed the risk adjustment model at the level of each stratification. This means that for the Emergency Medicine measure, the risk adjustment is applied to each combination of ED visit type and disposition status. For example, the risk adjustment model would assess separately a kidney and urinary episode that resulted in an inpatient stay, a kidney and urinary episode that resulted in a discharge, a fracture episode that resulted in an inpatient stay, and a fracture episode that resulted in a discharge.

Similar to other episode-based measures in use in the cost performance category and the episode-based measures proposed in this rule, we exclude episodes in cases where costs cannot be fairly compared to the costs for the whole cohort in the Emergency Medicine measure. For example, episodes are excluded for patients transferred to another ED facility from the triggering ED facility.

The proposed specifications for all five proposed episode-based measures are available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.* The specifications documents for each proposed measure consist of a methods document that describes the steps for constructing the measure and a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides detailed methodology describing each step to construct the measure, including: identifying patients receiving care, defining an episode-based measure, attributing episodes to MIPS eligible clinicians and clinician groups, assigning costs, defining exclusions, risk adjusting, and calculating measure score. Second, the measure codes list file contains the codes used in the measure specifications, including the episode triggers, attribution, stratification, assigned items and services, exclusions, and risk adjustors.

More information about the five proposed episode-based measures is available in the measure justification forms, which provide a comprehensive characterization of the measures, their justification, and testing results of these measures' specifications. These documents are available through the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We are seeking public comment on our proposal to add the five episode-based measures, which are listed in Table 43.

(b) Reliability and Case Minimum

In this section of the proposed rule, we discuss the proposed case minima to use for the five proposed episode-based measures and provide clarification on the interpretation of our regulation at § 414.1350(c) regarding the case minima for episode-based measures. Specifically, we propose a 20-episode case minimum for each of the five proposed measures based on our analysis of the reliability of each measure. We also provide clarification regarding application of our regulatory language under § 414.1350(c)(4) through (6). Currently, § 414.1350(c)(4) through (6) establishes the case minima for each type of episode-based measure (that is, procedural, acute inpatient medical condition, and chronic condition, respectively) beginning with a certain CY performance period/MIPS payment year specified therein. In this proposed rule, we are clarifying that the case minima established in § 414.1350(c)(4) through (6) applies to both the episode-based measure(s) we specified as beginning in the indicated performance period when the applicable regulatory provision was codified and for all episode-based measures of the same type that we specify to begin in subsequent performance periods, unless we specify otherwise for individual measure(s) in future rulemaking. We also note that, consistent with our past and current practice, we will continue testing the mean reliability of any potential episode-based measures that we propose to adopt in future rulemaking before applying the case minimum established in these regulations, as described later in this section.

Reliability is a metric that evaluates the extent that variation in a measure comes from clinician performance (''signal'') rather than random variation (''noise''). Higher reliability suggests that a measure is effectively capturing meaningful differences between clinicians' performance. However, we continue to caution against using reliability as the sole metric to evaluate a measure because of the tradeoffs between accuracy and reliability, and the role of service assignment in reducing noise. These and other considerations are detailed in the CY 2022 PFS final rule (86 FR 65453 through 65455). We also note that increasing case minima necessarily reduces the number of clinicians who meet the case minimum for a given measure. Because these are clinically refined measures, we aim to have as many clinicians as possible to be able to have their costs evaluated by them. Therefore, we consider that a mean reliability of 0.4 represents moderate reliability because it accounts for these considerations and is a sufficient threshold to ensure that the measure is performing as intended when assessed in conjunction with other testing.

We previously established at § 414.1350(c)(5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures in the CY 2019 PFS final rule (83 FR 59773 through 59774). We also established at § 414.1350(c)(6) a case minimum of 20 episodes for chronic condition episode-based measures in the CY 2022 final rule (86 FR 65453 through 65455). We have not adopted any care setting episode-based measures in the cost performance category, and therefore we have not established any case minimums for this type of episode-based measures. In this proposed rule, we considered a case minimum of 20 for each of the five proposed episode-based measures and then examined the reliability of the measures against this case minima.

We examined the reliability of the five proposed episode-based measures, and Table 44 presents the percentage of tax identification numbers (TINs) and TIN/National Provider Identifiers (NPIs) that meet the 0.4 reliability threshold and the mean reliability for TINs and TIN/NPIs at our proposed case minimum of 20 for each of the episode-based measures. At a 20-episode case minimum, the mean reliability for the

proposed Depression, Heart Failure, Low Back Pain, and Psychoses and Related Conditions measures exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. Similarly, at a 20-episode case minimum, the mean reliability for the proposed Emergency Medicine measure exceeds 0.4 for both groups and individual clinicians, and all groups and individual clinicians meet the 0.4 reliability threshold.

TABLE 44: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold and TIN and TIN/NPI Mean Reliability

Measure name (case minimum)	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Depression	99.62%	0.87	98.61%	0.80
Emergency Medicine	100.00%	0.91	100.00%	0.78
Heart Failure	91.81%	0.68	86.79%	0.60
Low Back Pain	96.27%	0.75	95.66%	0.73
Psychoses and Related Conditions	100.00%	0.83	100.00%	0.86

We believe that calculating these five proposed episode-based measures with these case minimums will accurately and reliably assess the performance of clinicians and clinician group practices. Therefore, we are proposing to adopt a case minimum of 20 episodes for each of the five proposed new episode-based measures. Given that we have not previously established any case minimums for the care setting episode-based measures, we also propose to codify the 20-episode case minimum for care setting episode-based measures under § 414.1350(c)(7).

Additionally, as we were reviewing our existing regulatory language under § 414.1350(c), we recognized the need to clarify the intended interpretation of the language because we acknowledge that the current framing is open to reasonable interpretation. Specifically, we clarify that the regulatory language at § 414.1350(c)(4) through (6) establishes the case minima for episode-based measures of each episode type (that is, procedural, acute inpatient medical condition, and chronic condition, respectively) such that the case minimum specified therein applies to all episode-based measures of that episode type, regardless of when the measure is adopted for inclusion in the cost performance category, unless otherwise specified for individual measure(s). For example, under § 414.1350(c)(6), the chronic condition episode-based measures that were specified beginning with the CY 2022 performance period/2024 MIPS payment year when this regulatory provision was codified (that is, the Diabetes and the Asthma/COPD measure) and any chronic condition episode-based measure specified after the CY 2022 performance period/2024 MIPS payment year will have a case minimum of 20 episodes, unless we specify otherwise for an individual measure.

We are proposing to update the regulatory language under § 414.1350(c)(4) through (6) to more clearly reflect this clarification. In addition, we are proposing that this interpretation will also apply to § 414.1350(c)(7) for care setting episode-based measures, which we are proposing under this section of this proposed rule.

We believe that it is appropriate to use case minimum based on the measure type for current and future measures in MIPS, as each measure episode type uses a consistent framework across measures so the case minimum should be also consistent, where possible. Additionally, consistent case minimum simplifies the level of information a MIPS eligible clinician or clinician group must monitor for the episode-based measures as the number of measures used in the cost performance category continues to grow. We note that for any future measure under consideration to be implemented in the cost performance category, case minima would still be evaluated against reliability testing, and could be different from the standard case minima established for the respective measure type under § 414.1350(c), as needed.

We are inviting comment on our proposals in this section IV.A.4.f.(2)(b), including our proposal to adopt these five episode-based measures in the cost performance category proposals and our interpretation of the existing regulatory language on the case minima for episode-based measures.

(c) Removal of Simple Pneumonia With Hospitalization Measure From the MIPS Cost Performance Category Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In this section of the proposed rule, we are proposing to remove the Simple Pneumonia with Hospitalization episode-based measure from the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year.

The Simple Pneumonia with Hospitalization episode-based measure was implemented for use in the MIPS cost performance category starting with CY 2019 performance period/2021 MIPS payment year (83 FR 59767 through 59773). Due to the impact of the COVID–19 pandemic, in accordance with § 414.1380(c)(2)(i)(A)(2), we assigned a weight of zero percent to the cost performance category for the CY 2020 performance period/2022 MIPS payment year and CY 2021 performance period/2023 MIPS payment year, and redistributed the prescribed weight to another performance category or categories, as established at § 414.1380(c)(2)(ii)(D). Therefore, no clinician or clinician group was scored on any episode-based measures, including the Simple Pneumonia with Hospitalization episode-based measure, for those 2 years.

For the CY 2022 performance period/2024 MIPS payment year, we announced via email communication

(subject: *2021 Quality Payment Program Experience Report and Infographic Now Available; Policy Update: Excluded MIPS Cost Measure for 2022 Performance Period*) on June 12, 2023, that in accordance with § 414.1380(b)(2)(v)(A), we would suppress the Simple Pneumonia with Hospitalization episode-based measure, so that eligible clinicians and clinician groups would not be scored on this measure for that performance period. This is a direct result of the International Classification of Diseases, Tenth Revision (ICD–10) coding updates related to COVID–19 that impacted the underlying population originally intended to be captured by this measure. Specifically, on January 1, 2021, an ICD–10 diagnosis code for pneumonia due to COVID–19 (J12.82) came into effect. Our guidance in the FY 2021 ICD–10–CM Official Guidelines for Coding and Reporting stated that this should be coded as secondary to COVID–19 (U07.1) (*https://www.cms.gov/files/document/2021-coding-guidelines-updated-12162020.pdf*). However, these two diagnosis codes (J12.82 and U07.1) map to different Medicare Severity Diagnosis Related Groups (MS–DRGs). J12.82 maps to the trigger codes for the Simple Pneumonia with Hospitalization measure (MS–DRGs 193–195, Simple Pneumonia and Pleurisy with MCC, with CC, and without CC/MCC, respectively), while U07.1 maps to Respiratory Infections and Inflammations (MS–DRGs 177–179, Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively), which are not used in this measure's trigger codes. That is, while this cost measure should include pneumonia due to COVID–19, it is unable to because it does not use MS–DRGs 177–179 in its trigger logic. For more information on the codes used to trigger Simple Pneumonia with Hospitalization measure episodes and the measure construction steps in general, please refer to the codes list file document available for download from the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

Once sufficient data became available from claims submitted in CY 2022 for our review and analysis, we conducted empirical testing. This empirical testing demonstrated that these coding changes have resulted in a marked decrease in the number of Simple Pneumonia with Hospitalizations episodes. Specifically, we have seen a significant decrease in the number of episodes, by almost half, as a direct result of this coding change. The measure does not use MS–DRGs 177–179 in its trigger logic and, therefore, the measure is unable to capture many pneumonia episodes, per the original measure intent. Empirical testing further showed that this significant decrease has resulted in many clinicians no longer meeting the 20-episode case minimum for attribution of the measure On these bases, we have excluded the Simple Pneumonia with Hospitalization measure from scoring for the CY 2022 performance period under § 414.1380(b)(2)(v)(A) because (1) these coding changes present a significant change external to care; and (2) these changes impacted calculation of the cost measures such that it would lead to misleading or inaccurate results, as demonstrated by the empirical analysis described in this section.

Given that these underlying coding issues affect the measure's ability to capture the intended population and that their uneven impact on MIPS eligible clinicians is expected to continue, we are proposing to remove the Simple Pneumonia with Hospitalization measure from the cost performance category beginning with CY 2024 performance period/2026 MIPS payment year. We do not believe that it is appropriate to continue to use the measure as currently specified without any changes to address the coding changes that formed our basis to suppress this measure in the CY 2022 performance period/2024 MIPS payment year. In other words, because we have already determined that the Simple Pneumonia with Hospitalization measure warranted exclusion under § 414.1380(b)(2)(v)(A) because the coding changes lead to misleading or inaccurate results in calculating the measure's score, it would be inappropriate to retain this measure for the CY 2024 performance period/2026 MIPS payment year as currently specified. This will continue to be true while the triggering methodology is specified in a way that is incongruous with billing practices. While we are exploring substantive changes to the measure's triggering methodology in response to the coding changes, the scope of these changes and the potential impacts of these changes on other elements of the measure require careful consideration and feedback from the Simple Pneumonia with Hospitalization Clinician Expert Workgroup and other interested parties prior to implementation. Because of these circumstances, we propose to remove the Simple Pneumonia with Hospitalization measure as it is currently specified from use in MIPS beginning with the CY 2024 performance period/2026 MIPS payment year.

We note that we have been comprehensively re-evaluating the Simple Pneumonia with Hospitalization measure, given the significant coding changes impacting calculation of this measure. The purpose of comprehensive re-evaluation is to ensure that measures continue to meet criteria for importance, scientific acceptability, and usability in line with the CMS Measures Management System Blueprint (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*). In this process, we holistically review the measure, seek public comment, and consider whether any changes need to be made to measure specifications after a measure has been in use for 3 years. A new version of the measure—Respiratory Infection Hospitalization—may be considered for implementation in MIPS in future years, after undergoing the pre-rulemaking and the notice-and-comment rulemaking processes. For more information on the re-evaluation efforts of the Simple Pneumonia with Hospitalization episode-based measure or other measures, please refer to the documents under the ''Wave 1 cost measure comprehensive reevaluation (2022–2023)'' section of the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We are inviting comments on this proposal.

(d) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

We are proposing revisions to the operational list of care episode and patient condition groups and codes to reflect the proposal of any new episode-based measures. Section IV.A.4.f.(2)(d) of this proposed rule provides context on the statutory requirements for care episode and patient condition groups and proposes changes to the operational list.

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups,

and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Medicare Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list of care episode and patient condition codes as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties.

For more information about past revisions to the operational list that we made as we developed and proposed episode-based measures, we refer readers to CY 2020 PFS final rule (84 FR 62968 through 62969) and CY 2022 PFS final rule (86 FR 65445 through 65461). The current operational list and prior operational lists is available at the QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

Additionally, as required by section 1848(r)(2)(I) of the Act, information on resource use (or cost) measures currently in use in MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of engagement with interested parties, and the percent of expenditures under Medicare Parts A and B that are covered by cost measures must be provided on the website of CMS not later than December 31 of each year.

In accordance with section 1848(r)(2)(H) of the Act, we are proposing to revise the operational list beginning with the CY 2024 performance period/2026 MIPS payment year to include five new care episode and patient condition groups, based on input from clinician specialty societies and other interested parties, as discussed in section IV.A.4.f.(2)(a)(ii) of this proposed rule. We propose including Emergency Medicine and Psychoses and Related Conditions as care episode groups and Heart Failure, Low Back Pain, and Depression as patient condition groups. These care episode and patient condition groups serve as the basis for the five new episode-based measures that we are proposing in section IV.A.4.f.(2)(a)(iii) of this proposed rule for the cost performance category. The codes that define these five care episode and patient condition groups align with the trigger codes of the proposed episode-based measures in section IV.A.4.f.(2)(a)(iii) of this proposed rule. As described in section IV.A.4.f.(2)(a)(ii), these specifications are developed with extensive input from interested parties.

Additionally, we propose to revise the operational list to remove the Simple Pneumonia with Hospitalization care episode group. As discussed in section IV.A.4.f.(2)(c)of this proposed rule, we are proposing to remove this episode-based measure from the cost performance category, so the codes that define this care episode group would no longer need to remain in the operational list.

Our proposed revisions to the operational list are available on our QPP Cost Measure Information page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Cost-Measures.*

We are inviting comments on this proposal.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), and the CY 2023 PFS final rule (87 FR 70057 through 70061). We also refer readers to 42 CFR 414.1305 for the definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We are not proposing any changes to the traditional MIPS improvement activities policies for the CY 2024 performance period/2026 MIPS payment year. We are proposing policies for group reporting in MIPS Value Pathways (MVPs). In addition, we are proposing changes to the improvement activities Inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing three previously adopted improvement activities.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities in line with statutory and program requirements. We discussed that we had conducted numerous interviews with highly performing organizations of all sizes and had conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category, including patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), CAHPS surveys, and AHRQ's Patient Safety Organizations. In addition, we reviewed the CY 2016 PFS final rule with comment period (80 FR 71259) and the comments received in response to the MIPS and APMs RFI in relation to the improvement activities performance category, which sought input on what activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

For the CY 2018 performance period/2020 MIPS payment year, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program CY 2018 performance period/2020 MIPS payment year and future years through subregulatory guidance.[315] In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for the CY 2019 performance period/2021 MIPS

[315] CMS, *Annual Call for Measures and Activities: Fact Sheet, https://www.cms.gov/Medicare/Quality-IniCtiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf.*

payment year and for future years, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the improvement activities Inventory. This process included the requirement to submit a nomination form similar to the one we utilized for the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing improvement activity, the interested party must submit a nomination form (OMB control # 0938–1314) available at *www.qpp.cms.gov* during the Annual Call for Activities.

(ii) Changes to the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix to the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 to the CY 2019 PFS final rule (83 FR 60286 through 60303), Tables A, B, and C in the Appendix 2 to the CY 2020 PFS final rule (84 FR 63514 through 63538), Tables A, B, and C in the Appendix 2 to the CY 2021 PFS final rule (85 FR 85370 through 85377), Tables A, B, and C in the Appendix 2 to the CY 2022 PFS final rule (86 FR 65969 through 65997), and Tables A, B, and C in the Appendix 2 to the CY 2023 PFS final rule (70633 through 70650) for our previously finalized improvement activities Inventories. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvement Activities&py=2022#measures* for a complete list of the current improvement activities. In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant interested parties identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

We are proposing to add five new improvement activities, modify an existing improvement activity, and remove three previously adopted improvement activities for the CY 2024 performance period/2026 MIPS payment year and future years. The proposed new and modified activities will help fill gaps we have identified in the Inventory, while the removal of three activities will help ensure that the Inventory reflects current clinical practice. We note that the proposed removal of one activity, IA_BMH_6, titled ''Implementation of co-location PCP and MH services,'' in the Behavioral and Mental Health subcategory is being proposed in order to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular. We also note that two of the five proposed new activities are in the Behavioral and Mental Health subcategory. We refer readers to Appendix 2 of this proposed rule for more details.

Four of the recommended new improvement activities are in the Population Management and the Behavioral and Mental Health subcategories. One proposed new activity, IA_PM_XX, titled ''Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services'' would allow MIPS eligible clinicians to receive credit for establishing policies and procedures to improve practice capacity to increase HIV prevention screening and linkage to appropriate prevention resources through taking action with the goals of increasing capacity to expand HIV prevention screening, improving HIV prevention education and awareness, and reducing disparities in pre-exposure prophylaxis (PrEP) uptake. Another activity, IA_PM_XX, titled ''Decision Support Improves Adherence to Cervical Cancer Screening and Management Guidelines'' would allow MIPS eligible clinicians to receive credit for incorporating cervical cancer clinical decision support (CDS) within the electronic health record (EHR) system. This activity leverages the convenience and efficiency of more sophisticated decision support tooling to assist clinicians in applying complex data-driven guidelines to provide optimal care and better engagement with their patient population, including historically underserved populations. This activity proposal was submitted by the CDC.

Two of the five proposed new activities are in the Behavioral and Mental Health (BMH) subcategory, reflecting this important Federal priority. IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women'' would allow MIPS eligible clinicians to receive credit for screening for perinatal mood and anxiety disorders (PMADs) and substance use disorder (SUD) in pregnant and postpartum women, as well as screening and referring to treatment and/or referring to appropriate social services in patient care plans. The second new activity being proposed in the BMH subcategory, IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults'' would allow MIPS eligible clinicians to receive credit for the completion of age-appropriate screening for mental health and substance use in older adults, as well as screening and referring to treatment and/or referring to appropriate social services in patient care plans.

Of the five proposed new improvement activities, four activities directly align with CMS' Priority 5 for advancing health equity, Increase All Forms of Accessibility to Health Care Services and Coverage. Therefore, the activities aim to create a fair and just opportunity for all people to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and/or other factors that affect access to care and health outcomes. These four proposed new improvement activities are the following: IA_PM_XX, titled ''Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services''; IA_PM_XX, titled ''Decision Support Improves Adherence to Cervical Cancer Screening and Management Guidelines''; IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women''; IA_BMH_XX, titled ''Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults.'' The fifth new proposed improvement activity is focused on MVP: IA_MVP, titled ''Practice-wide quality improvement in the MIPS Value Pathways Program (MVP).''

With the advent of MVPs, MIPS eligible clinicians can report measures that are more relevant to their specialized practice, including through subgroup reporting. The proposed IA_MVP activity would require a clinician to complete a formal model for quality improvement action that is linked to a minimum of three of the measures within the specific MVP. We believe this activity would expand and formalize quality improvement (QI) activities across practices, ultimately leading to improvements in quality of

care and fostering a culture of participation among staff. In addition, this activity would incentivize voluntary MVP adoption. It is important to note that, a clinician who reports an MVP can attest to the MVP improvement activity. However, a clinician in traditional MIPS is ineligible report the MVP improvement activity. Also, registration for an MVP is not sufficient for reporting the MVP improvement activity. Reporting the chosen MVP and attesting to having completed the necessary elements of the MVP improvement activity are both required. We refer readers to section IV.A.3.b(2). of this proposed rule for more information on MVPs.

We are proposing to modify one existing activity's description, titled ''Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs,'' and its validation criteria to explicitly promote the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS. Additionally, we are proposing to remove three previously finalized improvement activities to ensure that the improvement activities Inventory best reflects current clinical practice.

(iii) Improvement Activity Reporting Policies

Regarding group reporting, we are not revising group reporting policies for MVPs at this time. In the CY 2020 PFS final rule (84 FR 62981 through 62988) and codified at § 414.1360(a)(2), we finalized the policy that, beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of § 414.1360 must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable. Additionally, the NPIs must perform the same activity during any continuous 90-day period within the same performance year. We would like to clarify the relationship between a subgroup's successful completion of an improvement activity and its impact on the affiliated group. If a subgroup consists of 50 percent or more of the clinicians in the affiliated group, and the subgroup attests to completing an activity, then the group would receive credit for this improvement activity as this meets our standard for a group's completion of an improvement activity specified at § 414.1360.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the Promoting Interoperability performance category (and in past rulemaking, we referred to it as the advancing care information performance category).

For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to our regulation at § 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), and the CY 2023 PFS final rule (87 FR 70060 through 70087).

(b) Promoting Interoperability Performance Category Performance Period

In the CY 2021 PFS final rule (85 FR 84886), we established that for the CY 2024 MIPS payment year and each subsequent MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. We codified the policy at § 414.1320(g)(1) of our regulations, and subsequently re-designated that section as § 414.1320(h)(1) in the CY 2022 PFS final rule (86 FR 65671).

We are proposing that for the CY 2026 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 180-day period within CY 2024, up to and including the full CY 2024 (January 1, 2024, through December 31, 2024). This proposal would minimally increase the information collection burden on data submitters.

We believe that having additional data available from a longer performance period is beneficial to further improve the Promoting Interoperability performance category, and an integral step towards promoting health information exchange. Reporting on additional data during a longer performance period would provide MIPS eligible clinicians the opportunity to continuously monitor their performance, identify gaps in their reporting, and identify areas that may require their investigation and corrective action. We believe that requiring MIPS eligible clinicians to report additional data during a longer performance period will encourage MIPS eligible clinicians to produce more comprehensive and reliable data demonstrating that they are meaningful users of CEHRT.

Our long-term goal for the Promoting Interoperability performance category is to ensure the meaningful use of CEHRT and information exchange throughout the year, for all data, all clinicians, and all patients. Currently, when MIPS eligible clinicians select a 90-day performance period, this data is often not representative of their overall use of CEHRT throughout the entire calendar year. Instead, it reflects their best performing 90-days during the calendar year. In order for MIPS eligible clinicians to have a more accurate understanding of their overall performance, we want to move towards reporting on a full years' performance, which can be achieved by incrementally increasing the number of days in the performance period.

We continue to focus on patient safety, and the Promoting Interoperability performance category continues to focus on the safety and safe use of patient data by demonstrating the meaningful use of CEHRT. If a MIPS eligible clinician were to only focus on their best 90-day performance period, they may not focus on improving their overall performance in meaningfully using CEHRT throughout the year, and ultimately, observe, correct, and mitigate any potential patient safety concerns that may arise due to gaps in interoperability throughout the calendar year. If a MIPS eligible clinician does not meaningfully use CEHRT throughout the entire CY, there is a possibility for gaps in the transfer of key patient data necessary for supporting a diagnosis, continued treatment, or overall care planning.

Therefore, we are proposing to modify § 414.1320(h) for the Promoting Interoperability performance category performance period to remove the reference to subsequent years after the CY 2024 MIPS payment year, and instead specify that the policy applies only through the CY 2025 MIPS payment year. We further propose to add a new paragraph at § 414.1320(i)(1) to reflect our proposed performance period of a minimum of a continuous 180-day period within the calendar year

that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year for the Promoting Interoperability performance category, beginning with the CY 2026 MIPS payment year.

We are inviting public comment on our proposal to require a continuous 180-day performance period for the Promoting Interoperability performance category beginning with the CY 2024 performance period/2026 MIPS payment year, and the proposed changes to the regulation text at § 414.1320.

(c) Certified Electronic Health Record Technology Requirements

Section 1848(q)(2)(B)(iv) of the Act requires that, for the Promoting Interoperability performance category, the MIPS eligible clinician must meet the requirements established for the specified performance period under section 1848(o)(2) of the Act for determining whether the MIPS eligible clinician is a meaningful electronic health record (EHR) user. Section 1848(o)(2)(A) of the Act requires that, to be treated as a meaningful EHR user for an EHR reporting period for a payment year, a MIPS eligible clinician must be using certified EHR technology (CEHRT). Section 1848(o)(4) of the Act defines CEHRT as a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act, or PHSA) that is certified by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to section 3001(c)(5) of the PHSA in accordance with the certification standards that ONC adopted under section 3004 of the PHSA.

Accordingly, the MIPS Promoting Interoperability performance category regulation at § 414.1375(b)(1) requires a MIPS eligible clinician to use CEHRT as defined at § 414.1305 for the performance period. Since the CY 2019 performance period, in general, this has consisted of EHR technology (which could include multiple technologies) certified under ONC's Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102), and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition of CEHRT at § 414.1305.

As discussed in section III.R. of this proposed rule, in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule (88 FR 23758), which appeared in the April 18,2023 **Federal Register**, ONC has proposed to discontinue the year-themed ''editions,'' which ONC first adopted in 2012, to distinguish between sets of health IT certification criteria finalized in different rules. ONC is proposing to instead maintain a single set of ''ONC Certification Criteria for Health IT,'' which would be updated in an incremental fashion in closer alignment to standards development cycles and regular health information technology (IT) development timelines (88 FR 23750). As further discussed in section III.R. of this proposed rule, we are proposing to modify the definition of CEHRT for purposes of the Quality Payment Program at § 414.1305 to no longer refer to year-specific editions, and to incorporate any changes made by ONC to its definition of Base EHR and its certification criteria for health IT.

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

i. Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

We previously adopted the Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing (e-Prescribing) objective for the Promoting Interoperability performance category. For background on this measure, we refer readers to the CY 2019 PFS final rule (83 FR 59800 through 59803) and the CY 2020 PFS final rule (84 FR 62992 through 62994). In the CY 2021 PFS final rule (85 FR 84887 through 84888) and the CY 2022 PFS final rule (86 FR 65466 through 65467), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2021 and CY 2022 performance periods.

In the CY 2023 PFS final rule, we finalized our proposal to require the Query of PDMP measure beginning with the CY 2023 performance period, and that the measure will be worth 10 points (87 FR 70061 through 70067). In addition, along with other key specifications described in the CY 2023 PFS final rule, we removed the phrase ''except where prohibited in accordance with applicable law'' from the measure description, and established two exclusions beginning with the CY 2023 performance period: (1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; and (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period (87 FR 70061 through 70067). Finally, in the CY 2023 PFS final rule, we finalized a third exclusion for the Query of PDMP measure, but this exclusion was only available for the CY 2023 performance period/2025 MIPS payment year. (87 FR 70067)

The second exclusion is the same exclusion that we adopted for e-Prescribing measure in the CY 2018 PFS final rule (82 FR 53679). It has come to our attention that the second exclusion is problematic because it does not address situations where the MIPS eligible clinician does not electronically prescribe Schedule II opioids or Schedule III and IV drugs, in accordance with applicable law during the performance period, but does write more than 100 permissible prescriptions during the performance period. Therefore, we are proposing to modify the second exclusion criterion to state that any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period can claim the second exclusion.

We are inviting public comments on this proposal.

ii. Proposed Technical Update to the Electronic Prescribing Measure

The ONC 21st Century Cures Act final rule (85 FR 25660 through 25661) retired the ''drug-formulary and preferred drug list checks'' certification criterion at 45 CFR 170.315(a)(10), which was associated with measures under the Electronic Prescribing Objective for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (80 FR 62882 and 83 FR 59817). ONC retired this criterion after January 1, 2022, as provided in 45 CFR 170.550(m)(1) (85 FR 26661).

In the CY 2021 PFS final rule, we finalized that the ''drug-formulary and preferred drug list checks'' criterion will no longer be associated with measures under the Electronic Prescribing Objective and will no longer be required to meet the CEHRT definition for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, beginning with CY 2021 EHR reporting and performance periods (85 FR 84815 through 84825).

In the CY 2023 PFS final rule, we inadvertently omitted a revision to TABLE 92: Objectives and Measures for the Medicare Promoting Interoperability Performance Category for the CY 2023 performance period to reflect this change (87 FR 70075). In an effort to

more clearly capture the previously established policy finalized in the CY 2021 PFS final rule with respect to the e-Prescribing measure, we are proposing to revise the measure description as shown in Table 45 to read ''At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT'' and the numerator will be updated to read to indicate ''Number of prescriptions in the denominator generated and transmitted electronically using CEHRT'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks.''

We are inviting public comments on this proposal.

iii. Changes to the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Measure

A. Background

In the CY 2022 PFS final rule (86 FR 65475 through 65477), we adopted the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure under the Protect Patient Health Information Objective in the Promoting Interoperability performance category beginning with the CY 2022 performance period. ONC developed several SAFER Guides, including the High Priority Practices SAFER Guide, to help organizations at all levels conduct self-assessments which optimize the safety and use of EHRs. Under the SAFER Guides measure, MIPS eligible clinicians are currently required to attest to whether they have conducted an annual self-assessment using the High Priority Practices SAFER Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement. Beginning with the CY 2022 performance period, we required MIPS eligible clinicians to complete this attestation for this measure, though MIPS eligible clinicians are not scored based on their answer to the attestation or whether they fully complete the self-assessment. An attestation of ''yes'' or ''no'' is currently acceptable, and a MIPS eligible clinician can attest ''no'' without penalty. For additional information, please refer to our discussion of the SAFER Guides measure in the CY 2022 PFS final rule (86 FR 65475 through 65477).

B. Proposed Change to the SAFER Guides Measure

The SAFER Guides measure is intended to encourage MIPS eligible clinicians to use the High Priority Practices SAFER Guide, annually, to assess their progress and status on important facets of patient safety, including CEHRT implementation, safety and effectiveness, identifying vulnerabilities, and developing a ''culture of safety'' within their organization. For instance, the High Priority Practices SAFER Guide asks users to review and ensure that entries of allergies, problem lists, and diagnostic test results utilize standardized coding elements in their CEHRT (such as uniformly and consistently coding results as ''normal'' or ''high''). By ensuring their CEHRT consistently documents and codes health information, MIPS eligible clinicians confirm their CEHRT supports clear communication of a patient's health status, mitigating the risk of oversight, gaps, or potential safety risks introduced by the CEHRT, in the interoperable exchange of health information. By implementing the High Priority Practices SAFER Guide's recommended practices, MIPS eligible clinicians may be better positioned to operate CEHRT responsibly in care delivery, and to make improvements to the safe use of CEHRT as necessary over time.

Given our interest in promoting the safety and the safe use of CEHRT, we are proposing to amend the SAFER Guides measure to require MIPS eligible clinicians to conduct this self-assessment annually, and attest a ''yes'' response, accounting for completion of the self-assessment for the High Priority Practices SAFER Guide. The self-assessment should be completed between clinicians and staff members together, allowing MIPS eligible clinicians to see a snapshot of the status of the CEHRT used by their organization in terms of safety, and to identify areas needing improvement. Therefore, we are proposing to modify the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year such that only a ''yes'' response on the attestation will constitute completion of this measure, and a ''no'' response will result in a score of zero for the whole Promoting Interoperability performance category, indicating that the MIPS eligible clinician failed the requirements of the Promoting Interoperability performance category and is not a meaningful user of CEHRT. To reflect this proposal, we are proposing to modify our reporting requirements at § 414.1375 (b)(2)(ii)(C) to include ''For the 2024 MIPS payment year through the 2025 MIPS payment year'', and to add § 414.1375 (b)(2)(ii)(D), to say ''Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.''

We believe this proposed modification is feasible for MIPS eligible clinicians to implement, as they have had time to grow familiar with the use of the SAFER Guides under this measure by attesting either ''yes'' or ''no'' to conducting the self-assessment. We also note the availability of resources to assist MIPS eligible clinicians with completing the self-assessment as required by the SAFER Guides measure. One example of such resources is the SAFER Guides authors' paper titled ''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides,'' available without charge to download or use at *https://jamanetwork.com/journals/jama/fullarticle/2788984.*

Therefore, we are proposing to modify our requirements for the SAFER Guides measure beginning with the CY 2024 performance period and subsequent years, to require MIPS eligible clinicians to conduct, and therefore attest ''yes,'' an annual self-assessment of their CEHRT using the High Priority Practices SAFER Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs. Under this proposal, although the SAFER Guides measure would continue to be required with no associated points, an attestation of ''no'' would result in the MIPS eligible clinician not meeting the measure's requirements and therefore not a meaningful user of CEHRT, warranting a score of zero for the Promoting Interoperability performance category.

If our proposal to modify the SAFER Guides measure is finalized, we are also proposing to modify our reporting requirements at § 414.1375(b)(2)(ii)(C), and to add § 414.1375(b)(2)(ii)(D). Specifically, at § 414.1375(b)(2)(ii)(C), we propose to end our current requirements for the SAFER Guides measure with the 2025 MIPS payment year. Then, at § 414.1375(b)(2)(ii)(D), we propose to require, beginning with the 2026 MIPS payment year, that a MIPS eligible clinician submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

As a reminder, under the SAFER Guides measure, we do not currently require, and do not propose to require, MIPS eligible clinicians to attest to whether they have implemented any best practices ''fully in all areas'' as described in the High Priority SAFER Guide, nor will a MIPS eligible clinician be scored on how many of the practices they have fully implemented (86 FR 65475). We refer readers to Table 45 in this proposed rule for a description of the measure, and to the CY 2022 PFS final rule for additional background information (86 FR 65475 through 65477). Upon review of our current regulation governing reporting of the current SAFER Guides measure at § 414.1375(b)(2)(ii)(C), we identified areas where our regulation is unclear regarding the requirements for reporting the SAFER Guides measure. We are therefore also proposing to amend the regulatory text at § 414.1375(b)(2)(ii)(C) to specify clearly that a MIPS eligible clinician must submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs. As previously discussed, if our proposal to modify the SAFER Guides measure is finalized, this proposed regulatory provision would only be applicable for the 2024 MIPS payment year through the 2025 MIPS payment year.

We are inviting public comments on these proposals.

(e) Requirements for the Promoting Interoperability Performance Category for the CY 2024 Performance Period

i. Objectives and Measures for the CY 2024 Performance Period

For ease of reference, Table 45 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2024 performance period/2026 MIPS payment year as revised to reflect the policies proposed in this proposed rule.

TABLE 45: Objectives and Measures for the Promoting Interoperability Performance Category for the CY 2024 Performance Period

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.*	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.*	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. Any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.*
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other health care providers into their EHR using the functions of CEHRT	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health	Number of electronic summary of care records in the denominator for	Number of electronic summary of care records received using CEHRT for	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which

Objective	Measure	Numerator	Denominator	Exclusion
	Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA MIPS eligible clinicians would attest to the following: • Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. • Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the

Objective	Measure	Numerator	Denominator	Exclusion
				start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period:
Public Health and Clinical Data Exchange	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.	Security Risk Assessment: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

Objective	Measure	Numerator	Denominator	Exclusion
	security deficiencies as part of the MIPS eligible clinician's risk management process.			
Protect Patient Health Information	SAFER Guides High Priority Practices Guide: Conduct an annual assessment of the High Priority Practices Guide SAFER Guides*	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

* Signifies a policy proposed in this proposed rule.

ii. Scoring Methodology for the CY 2024 Performance Period

Table 46 reflects the scoring methodology for the Promoting Interoperability performance category for the CY 2024 performance period.

TABLE 46: Scoring Methodology for the CY 2024 Performance Period

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored. In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review, and attest to the actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

iii. Exclusion Redistribution

Many required measures have exclusions associated with them as shown on Table 45. If a MIPS eligible clinician believes that an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum points available in Table 46 do not include the points that will be redistributed in the event that a MIPS eligible clinician claims an exclusion. For ease of reference, Table 47 shows how points will be redistributed among the objectives and measures for the CY 2024 performance period in the event a MIPS eligible clinician claims an exclusion.

TABLE 47: Exclusion Redistribution for CY 2024 Performance Period

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
In addition, MIPS eligible clinicians must submit an attestation regarding ONC direct review, and attest to the actions to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3).

iv. 2015 Edition Health IT Certification Criteria

For ease of reference, Table 48 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2024 performance period and the associated 2015 Edition health IT certification criteria.

TABLE 48: Promoting Interoperability Performance Category Objectives and Measures and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition (CY 2024 Performance Period)
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

*The ONC 21st Century Cures Act final rule made changes to the existing 2015 Edition Health IT Certification Criteria by introducing new criteria and revising and removing existing criteria (85 FR 25667 through 25668). These changes are required for certified health IT used by MIPS eligible clinicians beginning with the CY 2023 performance period.

(f) Clinical Social Workers

In the CY 2022 PFS final rule (86 FR 65387 through 65389), we added clinical social workers to the definition of a MIPS eligible clinician under § 414.1305, beginning with the CY 2022 performance period/2024 MIPS payment year. Prior to the CY 2022 performance period, this clinician type was not eligible to participate in the Medicare Promoting Interoperability Program to earn incentive payments for meaningful use of CEHRT or receive reduced Medicare payments for failing to meaningfully use CEHRT. Clinical social workers were also not eligible for Medicaid EHR incentive payments.

In the CY 2022 PFS final rule (86 FR 65489), we stated that clinical social workers therefore may lack experience with the adoption or use of CEHRT, and that we believed there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to them. In the CY 2022 PFS final rule (86 FR 65489) and the CY 2023 PFS final rule (87 FR 70087), we established that we will apply to clinical social workers the same reweighting policy for the Promoting Interoperability performance category that we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians who are non-physician practitioners for the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year. Specifically, because we believed there may not be sufficient Promoting Interoperability performance category measures available and applicable to clinical social workers, pursuant to section 1848(q)(5)(F) of the Act, we assigned a weight of zero to the Promoting Interoperability performance category for clinical social workers. However, if a clinical social worker submits any data for any of the measures specified for the Promoting Interoperability performance category, then this category will not be reweighted to zero and we will score the clinical social worker on this category as part of their final composite performance score in accordance with § 414.1380(c)(1). This reweighting policy for clinical social workers is codified at § 414.1380(c)(2)(i)(A)(*4)(iii).*

Because CY 2022 was the first year that clinical social workers were included in our definition of MIPS eligible clinicians, we do not yet have any performance period data that we could use to evaluate whether the Promoting Interoperability performance category measures are applicable to this type of MIPS eligible clinician. In the CY 2023 PFS final rule (87 FR 70087), when we reweighted the Promoting Interoperability performance category for clinical social workers for the CY 2023 performance period/2025 MIPS payment year, we noted we would evaluate whether this reweighting policy should be continued for future years when we have performance period data available. Given that we do not have data from the CY 2022 performance period available to analyze at the time of this proposed rule, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2024 performance period/2026 MIPS payment year, and making the corresponding revisions to the regulatory text at § 414.1380(c)(2)(i)(A)(*4)(iii*).

We are inviting public comments on this proposal.

(5) APM Improvement Activities Performance Category Score

(a) Background

Section 1848(q)(5)(C) of the Act establishes specific scoring rules for the improvement activities performance category. Section 1848(q)(5)(C)(ii) of the Act provides that a MIPS eligible clinician who is in an Alternative Payment Model (APM), as defined in section 1833(z)(3)(C) of the Act, with respect to a performance period shall earn a minimum score of one half of the highest potential score for the improvement activities performance category. In accordance with section 1848(q)(5)(C)(ii) of the Act, we codified at § 414.1380(b)(3)(i) that individual MIPS eligible clinicians or groups who participate in an APM (as defined in section 1833(z)(3)(C) of the Act) for a performance period will earn at least 50 percent for the improvement activities performance category (81 FR 30132). With respect to MIPS eligible clinicians who participate in a MIPS APM for a performance period, we stated that they may receive an improvement activity score higher than 50 percent (81 FR 30132). Because we had identified all MIPS APMs as having met the improvement activity threshold score requirement, we noted that all MIPS APM participants will receive a score of 100 percent for the improvement activities performance category (85 FR 84865, 85031).

(b) Proposal

It has come to our attention that in the preamble of the CY 2021 PFS final rule (85 FR 84865) the terminology ''automatic'' was used in reference to the baseline score provided by section 1848(q)(5)(C)(ii) of the Act (85 FR 84865). This has led to an interpretation by some MIPS eligible clinicians that the baseline score represents ''credit'' that is ''automatically applied'' in all circumstances.[316] This is not how we intended this provision to function, and we wish to ensure that our rules do not automatically grant such ''credit''.[317] We are concerned that absent revisions the application of our current regulation may produce unintended or unexpected scoring outcomes for MIPS eligible clinicians and groups.

In order to prevent such scoring scenarios, we are proposing to amend § 414.1380 by revising paragraph (b)(3)(i) to require that, in order to initiate the baseline score for the improvement activities performance category, a MIPS eligible clinician or group with APM participation must have submitted data for two performance categories or attest to having completed an improvement activity. We are also proposing to amend § 414.1380 by adding paragraph (c)(2)(iv) to provide that we will not apply a baseline score if we have also approved a request for performance category reweighting or hardship exception affecting the improvement activities performance category, including MIPS EUC Exception applications under § 414.1380(c)(2)(i)(A)(*6*) or (C)(*2*), and automatic EUC events per § 414.1380(c)(2)(i)(A)(*8*) or (C)(*3*).

We believe that these proposals are necessary in part because § 414.1380(c)(2)(i)(A)(*6*) requires us to score any data submitted by a MIPS eligible clinician with an approved application-based hardship exception or who was identified as a clinician in a CMS-designated region affected by an automatic EUC event under §§ 414.1380(c)(2)(i)(A)(*6*), (A)(*8*), (C)(*2*), and (C)(*3*), regardless of whether that submission was for the purpose of MIPS final scoring. Based upon our current policies, a submission of data for the quality or Promoting Interoperability performance categories would initiate or prompt the calculation of a baseline

[316] For example, in the ''2022 Data Submission FAQs,'' available at *https://qpp.cms.gov/resources/resource-library*, we stated that MIPS eligible clinicians participating in APMs are eligible to receive ''automatic credit'' in the improvement activities performance category.

[317] Similarly, in the CY 2021 PFS final rule, we finalized a proposal to modify § 414.1380(b)(3)(ii) to make clear that the baseline score provided by section 1848(q)(5)(C)(i) of the Act for the improvement activities performance category is not automatically granted for clinicians participating in patient-centered medical homes and comparable specialty practices (83 FR 59868).

score for the improvement activities performance category, making the improvement activities category eligible for scoring. We believe that result is contrary to the purpose of hardship exceptions, such as the MIPS EUC Exception application provided by § 414.1380(c)(2)(i)(A)(*6*), which are designed to reweight the improvement activities performance category to zero percent.

We also believe this proposal would further our vision that ''the bedrock of the Quality Payment Program is high-quality, patient-centered care followed by useful feedback, in a continuous cycle of improvement'' (81 FR 77010). Generally speaking, through MIPS, we collect feedback based upon data and measures submitted for the quality, Promoting Interoperability, improvement activities, and cost performance categories. We need composite scores from at least two of those four performance categories in order for us to calculate a clinician's final score. There is no data submission requirement for the cost performance category—we use the Medicare claims data submitted by that clinician to calculate their cost-measure performance. Similarly, a MIPS eligible clinician is not required to submit detailed data for the improvement activities performance category; instead, a MIPS eligible clinician simply attests to having completed an activity or activities to report the performance category. We therefore believe that it is most appropriate for a MIPS eligible clinician to submit measurable data on the quality and Promoting Interoperability performance categories for the purpose of final scoring in order to be credited with the baseline score for the improvement activities performance category.[318]

We believe these proposals are timely in light of the proposal at section III.F.h.2. to require that Medicare Shared Savings Program (SSP) Accountable Care Organization (ACO) clinicians report the Promoting Interoperability performance category at the TIN level, as opposed to the APM Entity (that is, the, ACO) or individual level. If our existing policies are not amended, an SSP ACO clinician's submission of data to the Promoting Interoperability category will prompt the baseline score in the improvement activities performance category in every circumstance regardless of whether the clinician's group requested or otherwise qualified for reweighting of the performance categories. This proposal would allow us to conform to the general scoring expectation that, in the event the participant's request to reweight three or four performance categories to zero percent due to a hardship, per §§ 414.1380(c)(2)(i)(A)(*6*), (A)(*8*), (C)(*2*), and (C)(*3*), the participant would receive a final score equal to the performance threshold, resulting in a neutral payment adjustment, even if data are incidentally submitted for other performance categories.

In summary, we propose to amend § 414.1380 by revising paragraph (b)(3)(i) and adding paragraph (c)(2)(iv) to limit the application of baseline scores provided under section 1848(q)(5)(C)(ii) of the Act for the purpose of MIPS final scoring. We seek comment on these proposals.

g. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards with respect to applicable measures and activities specified for the four performance categories for a performance period and use such methodology to provide for a composite performance score for each such clinician for each performance period.

For the CY 2024 performance period/2026 MIPS payment year, we intend to continue to build on the scoring methodology we have finalized for prior years. This scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. In this proposed rule we are proposing to update our scoring policies consistent with this framework. Specifically, we propose to—

- Provide a technical update to § 414.1380(a)(1)(i) and (b)(1)(v)(A),
- Amend our criteria for assessing ICD–10 coding impacts under our scoring flexibilities policy; and
- Update our policies regarding Improvement scoring for the cost performance category.

We are not proposing changes to scoring policies for the Promoting Interoperability or improvement activities performance categories.

(b) Technical Updates

In the CY 2022 PFS final rule, we finalized proposals to remove measure bonus points for reporting additional high priority measures and using end to end electronic reporting beginning in the CY 2022 performance period/2024 MIPS payment year (86 FR 65504 through 65507). We updated corresponding regulation at § 414.1380(b)(1)(v)(B)(1)(iii) regarding the end to end measure bonus points, but not § 414.1380(a)(1)(i) regarding performance standards or § 414.1380(b)(1)(v)(A) regarding the high priority bonus points. Accordingly, we propose to revise § 414.1380(a)(1)(i) to provide that, measure bonus points for submitting high priority measures and using end-to-end reporting are available for performance periods and payment years prior to the CY 2023 performance period/2025 MIPS payment year. We also propose to revise § 414.1380(b)(1)(v)(A) to state that, beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points for submitting high priority measures.''

We refer readers to our regulation at § 414.1380 for our current policies on scoring. We request comments on these technical update proposals.

(c) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our current policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR65490 through 65509, and 87 FR 70088 through 70091). In the CY 2023 PFS final rule, we finalized policies to score administrative claims measures in the quality performance category using benchmarks calculate from data submitted during the associated performance period and clarified the topped-out measure lifecycle (87 FR 70088 through 70091).

[318] There is no data submission requirement for the quality and cost performance categories for a MIPS eligible clinician assessed under the facility-based measurement scoring methodology described in § 414.1380(e). Therefore, we would require that such clinicians report data on the Promoting Interoperability performance category (or attest to having completed an improvement activity) in order to prompt the baseline score for the improvement activities performance category.

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

We refer readers to CY 2018, CY 2019, Quality Payment Program final rules and the CY 2021, and CY 2022 PFS final rules (82 FR 53714 through 53716, 83 FR 59845 through 59847, 85 FR 84898 through 84901, and 86 FR 65491 and 65492 respectively) and § 414.1380(b)(1)(vii)(A) for our previously establish scoring flexibilities policy.

In the CY 2018 Quality Payment Program final rule (82 FR 53714 through 53716), we finalized that, beginning with the CY 2018 performance period, we will assess performance on measures considered significantly impacted by ICD–10 coding changes during the performance period based only on the first 9 months of the 12-month performance period. We stated that our determination as to whether a measure is significantly impacted by ICD–10 coding changes would include these factors: A more than 10 percent change in codes in the measure numerator, denominator, exclusions, and exceptions; clinical guideline changes or new products or procedures reflected in ICD–10 code changes; and feedback on a measure received from measure developers and stewards (82 FR 53714). We stated that 9 months of data is sufficient to assess performance when 12 months of data is not available. We finalized that we would publish a list of measures requiring 9 months of data on the CMS website by October 1st of the performance period if technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the CY 2020 performance period) (82 FR 53716).

In the CY 2019 Quality Payment Program final rule (83 FR 59845 through 59847), we finalized policies beginning with the CY 2019 performance period/ 2021 MIPS payment year to reduce the total available measure achievement points in the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise no longer be comparable to a historic benchmark. We wanted the flexibility to respond to instances in which the clinical evidence and guidelines change and approved measures no longer reflect the most up-to- date clinical evidence and could even result in a practice that is harmful to patients. We finalized expanding the list of reasons that a quality measure may be impacted during the performance period in addition to revising when we will allow scoring of the measure with a performance period truncation (to 9 months of data) or the complete suppression of the measure if 9 months of data are not available.

In the CY 2021 PFS final rule (85 FR 84898 through 84901), we finalized a consolidation of the CY 2018 and CY 2019 scoring flexibilities policies that allowed, beginning with the CY 2021 performance period/2023 MIPS payment year, truncation of the performance period or suppression of a quality measure respectively if CMS determines that revised clinical guidelines, measure specifications or codes impact clinician's ability to submit information on the measure or may lead to potentially misleading results. Based on the timing of the changes to clinical guidelines, measure specifications or codes, we will assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we will suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted.

In the CY 2022 PFS final rule (86 FR 65491), we finalized a policy to expand the situations in which the scoring flexibilities policies would be applied. This update revised § 414.1380(b)(1)(vii)(A) to change ''significant changes'' to ''significant changes or errors'' and to include the omission of codes or inclusion of inactive or inaccurate codes. Previous versions of the policy only included changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specification as impacts outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results and trigger application of this policy.

In this year's rule, we are proposing two modifications to the criteria by which we assess the impacts of ICD–10 coding changes. Firstly, we are proposing to eliminate the 10 percent ICD–10 coding change factor established in the CY 2018 Quality Payment Program rule (82 FR 53714). The quality and cost performance categories rely on measures that use detailed specifications that include ICD–10 code sets. We annually issue new ICD–10 coding updates, which are effective from October 1 through September 30. As part of this update, codes are added and removed from the ICD–10 code sets. When we adopted this standard in the CY 2018 Quality Payment Program final rule (82 FR 53714), we were concerned that ICD–10 coding changes in the final quarter of the performance period may render a measure no longer comparable to its historical benchmark. However, we have found that a 10 percent change to ICD–10 codes does not necessarily reflect a meaningful impact to clinicians' ability to report and be fairly scored on a quality measure. In the CY 2018 Quality Payment Program proposed rule, we discussed an approach where we would consider any change in ICD–10 coding to impact performance on a measure and thus only rely on the first 9 months of the 12-month performance period for such measures; however, we stated that such an approach was too broad (overly inclusive of changes) and would truncate measurement for too many measures where performance may not be significantly affected (82 FR 30098). We maintain this perspective but have concluded that a 10 percent change in codes is similarly over inclusive as it leads to the suppression of measures that can still be scored using all 12 months of the performance period. In place of the 10 percent threshold we propose to assess the overall impact on a measure resulting from changes to ICD–10 codes. Rather than consider a flat 10 percent change as a factor for when ICD–10 coding changes affect a measure, we would instead assess how the coding changes affect the measure numerator, denominator, exclusions, and exceptions in ways that could lead to misleading or harmful results. We would assess whether resultant changes to the numerator, denominator, exceptions, exclusions, or other measure elements change the scope or intent of the measure.

Changes in measure scope or intent would be considered significant changes that affect the applicability of the historical benchmark. ICD–10 codes include information related to clinical diagnoses and eligible patient population. For example, ICD–10 codes in the denominator correspond to the total eligible patient population considered for a measure. If as a result of a clinical guideline change a code is changed from an exclusion to a code to be considered in the total patient population indicated in the denominator for a measure, this would meaningfully change the scope of the measure and could lead to misleading results in measurement. Additionally, instances in which coding changes change the designation of whether performance was met or not (numerator)

could similarly lead to misleading results. These changes would be considered significant and therefore trigger our scoring flexibilities policy.

Second, we are proposing to assess the impacts of coding changes and our associated course of action (suppression, truncation, or standard 12-month reporting) by measure collection type. Our scoring policy states that we calculate benchmarks by collection type (§ 414.1380(b)(1)(ii). As benchmarks are assessed by collection type, we must consider by collection type whether the changes or errors will result in patient harm or misleading results.

Each collection type has different technical limitations. For example, measure specifications for the MIPS CQMs and Medicare Part B claims collection types can be updated in the performance period immediately following the publication each October of changes to ICD–10 codes. If an ICD–10 coding change occurs in October of 2024, CMS can immediately update the specifications for the measure's MIPS CQMs and Medicare Part B claims collection types and the ICD–10 changes would not result in any misleading results for the measure for those collection types.

This differs from eCQM measure specifications, which are posted in the May the year before the measure specifications take effect and are valid for the 12-month reporting period. For the CY 2024 performance period/2026 MIPS payment year, eCQM measures specifications will be posted in May of 2023 and are valid for the applicable 12-month performance period in CY 2024. In the example given above, the measure's eCQM collection type would not be updated again until May 2025 for the CY 2026 performance period/2028 MIPS payment year, and clinicians would be left reporting pursuant to outdated specifications for the final quarter of the CY 2024 performance period. This could result in misleading results for the measure's eCQM collection type. As a result, it would be appropriate for CMS to assess the impact of changes to measures and implement the appropriate scoring flexibility by collection type.

Lastly, we are proposing that measure specifications for eCQMs include the capability to be truncated to a 9-month performance period. Current measure specifications for eCQMs provide exclusively for a 12-month reporting period. If a measure is significantly impacted by ICD–10 coding changes, it therefore cannot be reported for a truncated performance period of 9-month. In order to implement the scoring flexibilities policy as intended and protect our ability to score measures where 9 consecutive months of data is available, we propose to begin requiring measure specifications to include logic for a 9-month performance period in addition to the currently existing 12-month performance period.

These updates will help us to better provide scoring flexibilities to clinicians by being sensitive to the particular impacts to and capabilities of the particular quality measures collection types. We seek comment on our proposal to update the criteria by which be apply scoring flexibilities in response to ICD–10 coding changes.

(d) Cost Performance Category Score

(i) Improvement Scoring Methodology

(A) Background

Section 1848(q)(5)(D)(i) requires that, if sufficient data are available to measure a MIPS eligible clinician's improvement in the quality and cost performance categories, then our methodology for computing the final score must take into account such improvement. In the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), we established policies related to measuring improvement in the cost performance category at the measure level, an improvement scoring methodology for the cost performance category, and a formula for calculating the cost performance category percent score to include achievement and improvement. These policies were to apply beginning with the CY 2018 performance period/2020 MIPS payment year. We codified these policies at 42 CFR 414.1380(b)(2)(iii) and (iv) (82 FR 53748 through 53752, 53957).

Subsequent to the publication of the CY 2018 Quality Payment Program final rule, the Bipartisan Budget Act of 2018 (BBA 18) (Pub. L. 115–123, February 9, 2018) was enacted. Section 51003(a)(1)(B) of the BBA 18 added a new clause at section 1848(q)(5)(D)(iii) of the Act which provided that the cost performance category score shall not take in to account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments (the CY 2018 performance period/2020 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year).

To implement these statutory changes, in the CY 2019 PFS final rule (83 FR 35956, 36080 through 36082), we established that the maximum cost improvement score for the CY 2018 performance period/2020 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year is zero percentage points, which we codified at § 414.1380(a)(1)(ii) and (b)(2)(iv)(E). In the CY 2023 PFS final rule (87 FR 70091 through 70093, 70228), we stated that we would begin to implement cost improvement scoring in the CY 2022 performance period/2024 MIPS payment year and established that the maximum cost improvement score available would be 1 percentage point. We codified this policy at § 414.1380(b)(2)(iv)(E). In addition, under our authority at § 414.1380(c)(2)(i)(A)(8), we reweighted the cost performance category's score to zero percent of the final score for the CY 2019 performance period/2022 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year due to the COVID–19 Public Health Emergency (PHE) (85 FR 19277 through 19278; See ''Extension to Data Submission Deadline'' on Quality Payment Program website at *https://qpp.cms.gov/*). On these bases, to date, we have not applied a cost improvement score to MIPS eligible clinicians' final scores in accordance with the policies we established in the CY 2018 Quality Payment Program final rule and our regulations at § 414.1380(b)(2)(iii) and (iv). (*https://qpp.cms.gov/*).

(B) Description of Previously Finalized Cost Improvement Scoring Methodology

As discussed previously in this section, we established several policies related to our calculation and application of cost improvement scores to MIPS eligible clinicians' final scores in the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752). First, we established that we would determine the cost improvement score at the individual measure level, instead of the performance category level, for the cost performance category (82 FR 53749 through 53750). Second, we established our methodology for calculating the cost improvement score, generally by comparing the number of cost measures with significant improvement in performance and the number of cost measures with significant declines in performance for a MIPS eligible clinician or group between two consecutive performance periods (82 FR 53750 through 53752). Specifically, we established that we would quantify the cost improvement score by subtracting the number of cost measures with a significant decline from the number of cost measures with a significant improvement, and then dividing the result by the number of cost measures for which the MIPS eligible clinician or group was scored

for two consecutive performance periods, and then multiply the resulting fraction by the maximum improvement score (82 FR 53750 through 53752). We further established that we would determine whether there was significant improvement or decline in performance between the two performance periods by applying a common standard statistical test to measure significance, the t-test, as used in the Shared Savings Program (82 FR 53750 through 53752). Finally, we established that the cost improvement score cannot be lower than zero percentage points (82 FR 53750 through 53752).

We codified our cost improvement scoring policies at § 414.1380(b)(2)(iv). These policies governing our cost improvement scoring methodology have not been modified since the CY 2018 Quality Payment Program final rule.

(C) Mathematical Feasibility Issue for Cost Improvement Scoring Methodology

In reviewing our cost improvement scoring methodology, we discovered that calculating cost improvement scoring based on comparing only cost measures with a statistically significant change, determined by using a t-test, is not congruent with the underlying data. A t-test compares how significant the differences are between group means, which are aggregate values, and cannot compare how significant the differences are between single values. However, our current cost improvement methodology set forth at § 414.1380(b)(2)(iv) requires comparing a MIPS eligible clinician's scores for an individual cost measure, which are single value points rather than group means. Further, the current methodology purports to compare those single value points between two consecutive performance periods to determine if there has been a statistically significant change (improvement or decline) in performance. Therefore, a t-test cannot be applied to the single cost measure score data points for consecutive time periods to determine if a statistically significant change has occurred, rendering our cost improvement scoring methodology mathematically infeasible.

When we initially developed the cost improvement scoring methodology for the cost performance category, there were only two population-based cost measures (total per capita cost and Medicare Spending per Beneficiary measures), and no episode-based measures. As of the CY 2023 performance period/2025 MIPS payment year, there are 23 episode-based cost measures in addition to the two population-based measures. We expect to add additional episode-based measures to the cost performance category in future years as MIPS matures.

We believe that the aggregated nature of the two population-based measures influenced our determination regarding the feasibility of establishing statistical significance, using a t-test, when we developed and established the cost improvement scoring methodology. However, although these population-based measures are aggregated measures, they are calculated as individual single values in time, and not aggregate values which the t-test requires, for a specific clinician for each of the two consecutive performance periods. Further, considering a method using statistical significance might have been an oversight because of the lack of episode-based measures when the cost improvement scoring method was developed.

Because we have not implemented cost improvement scoring since we finalized this methodology in the CY 2018 Quality Payment Program final rule as discussed in section (4)(a)(iv) of this proposed rule, we failed to identify that the currently established cost improvement scoring method is not mathematically feasible. We identified the mathematical infeasibility of the current cost improvement methodology in the process of implementing cost improvement scoring for the CY 2023 performance period/2025 MIPS payment year.

(D) Operational Feasibility Issues for Cost Improvement Scoring Methodology

In addition, in the process of implementing cost improvement scoring for the CY 2023 performance period/2025 MIPS payment year, we identified three issues with our current policy at § 414.1380(b)(2)(iv)(A) because we determine each MIPS eligible clinician's cost improvement score at the individual cost measure level, and not the category level, for the cost performance category. To address these three issues, further specified herein, we propose to revise this policy so that we will determine the cost improvement score at the category level, instead of the cost measure level, for the cost performance category.

- Measure level improvement scoring implementation issue: The growing number of cost measures brings into question if using the current methodology for cost improvement scoring introduces complexities to its implementation, which in turn brings into question operational feasibility. When the methodology was established, in the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), there were only two cost measures. As of the CY 2023 performance period/2025 MIPS payment year, there are 25 cost measures; we expect to add additional measures to the cost performance category as MIPS matures. Maintaining measure level improvement scoring, for a performance category that will continue to see growth in the number of measures, would be resource intensive, complex to implement, and error prone. Specifically, every measure would need its own workflow and testing, which would increase the amount of work to ensure year-over-year comparisons are accurate and increase risk of calculation or data errors. Further, maintaining measure level cost improvement scoring would introduce the same operational complexities we see in benchmarking measures, particularly when a measure encounters significant change from one year to the next—a reality that might present in future MIPS performance years. These challenges support our proposal to changing improvement scoring from measure level to category level for the cost performance category.
- Performance category improvement scoring consistency: As set forth at § 414.1380(b)(1)(vi)(C), we calculate each MIPS eligible clinician's improvement score for the quality performance category in MIPS at the performance category level. Upon further evaluation, we found that using two different methods of improvement scoring for the quality and cost performance categories would increase the implementation cost and operational complexity described above—as well as confuse MIPS eligible clinicians and call into question why we use two different methodologies. As such, we concluded that using category level assessment for cost improvement scoring would establish consistency across MIPS and allow effective communication with MIPS eligible clinicians, while reducing implementation cost and operational complexity.
- Fairness of improvement scoring: The episode-based measures for the cost performance category are specific to certain clinical conditions and/or care settings. Some MIPS eligible clinicians might not have the sufficient volume threshold for any or all of the episode-based measures for two consecutive performance periods, making year over year improvement scoring at the measure level less viable. Measure level improvement scoring might negatively impact these clinicians' overall cost performance category scoring because of the inclusion of episode-based measures outside of their scope of practice.

Further in the CY 2018 Quality Payment Program final rule (82 FR 53750) we received comments in favor of category level assessment for cost improvement scoring because of concerns with the inclusion of episode-based measures and their potential growth for the cost performance category. Specifically, the concerns highlighted that determining improvement scoring at the measure level might be unfair; it would be difficult for all MIPS eligible clinicians to demonstrate improvement across all measures. A category level assessment provides an equitable cost improvement scoring for MIPS eligible clinicians with different scopes of practice because it would only reflect measures that are applicable to them.

(E) Proposed Modifications for Cost Improvement Scoring Methodology Beginning With the CY 2023 Performance Period/2025 MIPS Payment Year

In light of both the mathematical and operational feasibility issues with our current cost improvement scoring methodology, we are proposing two modifications beginning with the CY 2023 performance period/2025 MIPS payment year.

First, we propose to determine each MIPS eligible clinician's cost improvement score at the category level, instead of the current measure level, beginning with the CY 2023 performance period/2025 MIPS payment year. We propose this modification based on the operational feasibility considerations previously discussed. We also propose that, if this proposal is finalized, § 414.1380(b)(2)(iv)(A) and (C) would be amended to reflect that the cost improvement score will be determined at the category level for the cost performance category. In addition, we propose that, if this proposal is finalized, § 414.1380(b)(2)(iv)(B) would be amended to reflect that we would determine whether sufficient data are available to measure improvement to calculate the cost improvement score based on whether a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive performance periods.

Second, we propose to modify the cost improvement scoring methodology to remove the requirement that we compare measures with a ''statistically significant change (improvement or decline) in performance'' as determined based on application of a t-test beginning with the CY 2023 performance period/2025 MIPS payment year. As previously discussed in section IV.A.4.g.(1)(d)(i)(C) of this proposed rule, determining cost improvement scoring based on statistical significance, using a t-test, is not congruent with our underlying data and is mathematically infeasible.

As such, we are proposing to remove the statistical significance requirement and update the calculation on how we quantify cost improvement scoring accordingly. Specifically, at § 414.1380(b)(2)(iv)(C), we are proposing to determine the cost improvement score at the category level by subtracting the cost performance category score from the previous performance period (for example, CY 2022 performance period/2024 MIPS payment year) from the cost performance category score from the current performance period (for example, CY 2023 performance period/2025 MIPS payment year), and then by dividing the difference by the cost performance category score from the previous performance period (for example, CY 2022 performance period/2024 MIPS payment year), and by dividing by 100.

In our current and established policy set forth at § 414.1380(b)(2)(iii), the overall cost performance category score for the current year with the improvement assessment is based on the following calculation: Cost Performance Category Score = Current Year Performance Score + Improvement Score. We do not propose any changes to this established policy.

The following is an example to illustrate how the cost improvement score will be calculated if our two proposals to modify our cost improvement scoring policies are adopted. An individual clinician, using the same identifier (TIN A/NPI 1) for two consecutive performance periods, has a cost performance category score of 52.00 percent from the previous year, and 63.71 percent in the current year. Using our proposed change, at § 414.1380(b)(2)(iv)(C), to determine the cost improvement score at the category-level, without using statistical significance, the first step is to quantify the change between current performance period score and the previous performance period score. This is 63.71 percent − 52.00 percent, which equals 11.71 percent. Then, the cost improvement score is determined as follows: ((change between current and previous year performance scores/previous year performance score))/100. This is ((11.71 percent/52 percent)/100). Therefore, the cost improvement score for the current year is 0.23 percentage points.

TABLE 49: Example of Assessing Improvement in the Cost Performance Category

Performance Year	Clinician	Performance Score	Change between Current and Previous Years	Improvement Score
Previous Year	TINA/NPI 1	52.00%	-	-
Current Year	TINA/NPI 1	63.71%	11.71%	0.23 pp

*pp = percentage point

Based on our current and established policy, set forth at § 414.1380(b)(2)(iii), the overall cost performance category score for current performance period is current year performance score + improvement score. This is 63.71 percent + 0.23 percentage point, which equals 63.94 percent.

Lastly, to determine how many points the cost performance category contributes to the final score as set forth in § 414.1380(c)(1), the current year cost performance category score (63.94 percent) is multiplied by the weight of the cost performance category (30 percent of the final score) and by 100 to determine the points to the final score. The individual clinician would have 63.94 percent × 30 percent × 100 = 19.18 points cost performance category contribution to the final score.

We are proposing that these two modifications to our cost improvement scoring policy would be effective

beginning with the CY 2023 performance period/2025 MIPS payment year. As discussed previously in section IV.A.4.g.(1)(d)(i)(A) of this proposed rule, section 1848(q)(5)(D)(i) of the Act requires that we account for a MIPS eligible clinician's improvement in the cost performance category if we have sufficient data available to measure improvement. Because we have not implemented cost improvement scoring to date, we did not have sufficient data available to measure year-over-year improvement scoring for the cost performance category until the CY 2023 performance period/2025 MIPS payment year. However, we do have such sufficient data available beginning with the CY 2023 performance period/2025 MIPS payment year. Further, section 1848(q)(5)(D)(iii) of the Act, requiring that we delay our implementation of cost improvement scoring through the CY 2021 performance period/2023 MIPS payment year, no longer applies. Therefore, we are proposing to implement cost improvement scoring, with these two proposed modifications, beginning with the CY 2023 performance period/2025 MIPS payment year.

On this basis, we are proposing to amend § 414.1380(b)(2)(iv)(E) to state that the maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment years is zero percentage points and that the maximum cost improvement score beginning with the CY 2025 MIPS payment year is 1 percentage point. In addition, we are proposing to amend § 414.1380(a)(1)(ii) to state that improvement scoring is available in the cost performance category starting with the 2025 MIPS payment year, instead of the 2024 MIPS payment year. The remainder of the language currently at § 414.1380(a)(1)(ii) will remain the same.

We are soliciting public comment on these proposals.

f. MIPS Payment Adjustments

(1) Background

Section 1848(q)(6)(A) of the Act requires that we specify a MIPS payment adjustment factor for each MIPS eligible clinician for a year. This MIPS payment adjustment factor is a percentage determined by comparing the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor.

For previously established policies regarding our determination and application of MIPS payment adjustment factors to each MIPS eligible clinician, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2022 PFS final rule (86 FR 65527 through 65537), and CY 2023 PFS final rule (87 FR 70096 through 70102).

In the CY 2023 PFS final rule (87 FR 70096 through 70102), we established the performance threshold for the CY 2023 performance period/2025 MIPS payment year by calculating the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data. In addition, we included information about our timing for providing MIPS performance feedback to MIPS eligible clinicians for the CY performance period in accordance with section 1848(q)(12) of the Act.

(2) Establishing the Performance Threshold

(a) Statutory Background and Authority

As discussed above, in order to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with Section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years.

Sections 1848(q)(6)(D)(ii) through (iv) of the Act provided special rules, applicable only for certain initial years of MIPS, for our computation and application of the performance threshold for our determination of MIPS payment adjustment factors. Specifically, for the CY 2017 performance period/2019 MIPS payment year through CY 2022 performance period/2024 MIPS payment year, section 1848(q)(6)(D)(ii) of the Act required that we establish an additional performance threshold for determining additional positive MIPS payment adjustment factors applicable to MIPS eligible clinicians with exceptional performance. Then, for the CY 2017 performance period/2019 MIPS payment year through CY 2021 performance period/2023 MIPS payment year, section 1848(q)(6)(D)(iii) required that we establish a performance threshold based on a period prior to such performance periods and take into account available data with respect to performance on measures and activities that we may use under the four MIPS performance categories and other factors determined appropriate by the Secretary. Specifically, section 1848(q)(6)(D)(iii) of the Act addressed how we would establish a performance threshold for MIPS in its initial years prior to having final score data available from prior periods of MIPS. Finally, for the CY 2019 performance period/CY 2021 MIPS payment year through CY 2021 performance period/2023 MIPS payment year, section 1848(q)(6)(D)(iv) of the Act required that we methodically increase the performance threshold each year to ''ensure a gradual and incremental transition'' to the performance threshold we estimated would be applicable in the CY 2022 performance period/2024 MIPS payment year. Although sections 1848(q)(6)(D)(ii) through (iv) of the Act are no longer applicable for establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year, these previously applicable statutory requirements explain our prior computations of the performance threshold that impact our policy considerations for establishing the performance threshold for MIPS going forward.

In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean as the methodology for determining the performance threshold for the CY 2022 through 2024 performance periods/2024 through 2026 MIPS payment years. We also established in our regulation at 42 CFR 414.1405(g) that, for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS

payment year, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period. For CY 2022 through CY 2023 performance periods/2024 through 2025 MIPS payment years, we selected a single performance period when selecting a prior period to compute the mean of the final scores and establish the performance threshold. However, as discussed under paragraph (b) of this section, we propose to modify and refine our policy for selecting a ''prior period'' to establish the performance threshold under paragraph (b) of this section.

For further information on our current performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53792), CY 2019 PFS final rule (83 FR 59879 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), CY 2022 PFS final rule (86 FR 65527 through 65532), and CY 2023 PFS final rule (87 FR 70096 through 70100).

We codified the performance thresholds for each of the first 7 years of MIPS at § 414.1405(b)(4) through (9). These performance thresholds are shown in Table 50.

TABLE 50: Performance Thresholds for the CY 2017 through CY 2023 Performance Periods/2019 through 2025 MIPS Payment Years

MIPS Performance Period	2017 MIPS Performance Period	2018 MIPS Performance Period	2019 MIPS Performance Period	2020 MIPS Performance Period	2021 MIPS Performance Period	2022 MIPS Performance Period	2023 MIPS Performance Period
Year of MIPS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Performance Threshold	3 points	15 points	30 points	45 points	60 points	75 points	75 Points
Change from prior year	N/A	12 points	15 points	15 points	15 points	15 points	0 points

(b) Proposal To Modify Our Policy for Establishing the Performance Threshold Beginning With the CY 2024 Performance Period/2026 MIPS Payment Year

In previous years, we selected a single performance period when selecting a prior period. In this proposed rule, we are reassessing our previous interpretation of ''prior period'' as described at section 1848(q)(6)(D)(i) of the Act.

Section 1848(q)(6)(D)(i) states that the performance threshold for a year shall be the mean or median (as selected by the Secretary) of the composite performance scores for all MIPS eligible professionals with respect to a ''prior period'' specified by the Secretary. The use of ''prior period'' in section 1848(q)(6)(D)(i) of the Act differs from other provisions in the statute which specifically refer to ''a year'' or ''performance period.'' For example, section 1848(q)(6)(A) of the Act specifies application of a MIPS adjustment factor for ''a year.'' Meanwhile, section 1848(q)(4) of the Act specifically defines the term ''performance period'' for MIPS, requiring that the Secretary shall establish ''a performance period (or periods) for a year (beginning with 2019)'' and such ''performance period (or periods)'' shall begin and end prior to the beginning of such ''year and be as close as possible to such year.'' These statutory provisions governing MIPS clearly distinguish the terms ''performance period'' and ''year'' from ''prior period'' used in section 1848(q)(6)(D)(i) of the Act. If the ''prior period'' we use to determine the mean or median of all MIPS eligible clinicians' final scores to establish the performance threshold under section 1848(q)(6)(D)(i) of the Act was intended to be limited to a single year or performance period, we believe the statute would have been more specific on that point rather than using the unique term, ''prior period.''

Because section 1848(q)(6)(D)(i) of the Act does not specifically refer to ''a performance period'' or ''year'' to establish the performance threshold, we believe that the term ''prior period'' can refer to a time span other than a single year or performance period as long as that ''prior period'' is specified by the Secretary. More specifically, given our interpretation that ''prior period'' does not require CMS to select a single performance year as the period, we propose to add § 414.1405(g)(2) to specify that, beginning with CY 2024 performance period/2026 MIPS payment year, a ''prior period'' for purposes of establishing a performance threshold as identified in § 414.1405(b) is a time span of 3 performance periods. Subsequently, we also propose to redesignate language at § 414.1405(g) which states that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section, as § 414.1405(g)(1).

Recognizing the flexibility of the term, ''prior period,'' we reviewed the data we have available from prior MIPS performance periods, and believe it would be appropriate to specify a ''prior period'' as three performance periods. Using three performance periods as the prior period would prevent the performance threshold from being dependent on a single potentially anomalous performance period, or on two performance periods, whose mean or median final score may be an outlier compared to other performance periods. The mean or median of final scores over 36 months is less likely to be impacted by unusual fluctuations in performance specific to a shorter time frame, is more likely to reflect clinician performance, and therefore, more appropriate to set the performance threshold. Using the mean or median of final scores of three performance periods would allow us to include more scores in the computation of the mean or median, and therefore, mitigate the impact of outliers. Further, using three performance periods would also smooth out year-to-year fluctuations in the performance threshold, developing greater consistency and stability in MIPS, and providing more predictability for MIPS eligible clinicians who may wish to set MIPS performance goals. Additionally, as more data become available, we will consider whether a longer time span than three performance periods may be

appropriate to mitigate outliers and better reflect clinician performance trends.

In the CY 2022 PFS final rule (86 FR 65531 through 65532), we stated that, under our interpretation of section 1848(q)(6)(D)(i) of the Act at that time, choosing the mean or median from a ''prior period'' does not allow us to balance scores from multiple years. However, on further reflection, the presence of distinctions in the statute between ''prior period'' and ''performance period'' and ''year'' has prompted us to reevaluate the appropriateness of limiting our establishment of the performance threshold based on a single prior performance period.

We request comments on our proposal to use three performance periods as the ''prior period'' we use to establish a performance threshold and codify the policy at § 414.1405(g)(2).

(c) Performance Threshold for the CY 2024 Performance Period/2026 MIPS Payment Year

While we chose to use the mean in our methodology for determining the performance threshold for the CY 2022 through 2024 performance periods/2024 through 2026 MIPS payment years, we have not specified which prior period's mean final score we would use for the CY 2024 performance period/2026 MIPS payment year's performance threshold. From our review of the data available to us, we identified the mean final scores for each of the CY 2017 through 2021 performance periods/2019 through 2023 MIPS payment years individually, as well as the mean of the final scores for CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years combined, as shown in Table 51. Based on our proposed definition of ''prior period,'' we included means of final scores for MIPS eligible clinicians spanning over three performance periods within Table 51 in addition to a single year performance period. These six values represent the mean final scores for all MIPS eligible clinicians from prior periods that are available for consideration for the CY 2024 performance period/2026 MIPS payment year performance threshold.

We are not considering the means of the final scores for certain prior periods because of issues with the underlying data. First, for the CY 2020 through 2021 performance periods/2022 through 2023 MIPS payment years for the purpose of establishing the performance threshold because we extensively applied our extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE, which we believe resulted in skewing the final scores from those years such that they are not an appropriate indicator for future clinician performance. We announced on April 6, 2020, the application of extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE for the CY 2019 performance period/2021 MIPS payment year (85 FR 19277 through 19278). However, given the timing of the COVID–19 PHE and this announcement, the data was likely minimally impacted because many MIPS eligible clinicians had already submitted the data. Second, the final scores for the CY 2022 performance period/2024 MIPS payment year were not finalized in time for this proposed rule and, therefore, the mean final score for the CY 2022 performance period/2024 MIPS payment year is not included for consideration as a potential performance threshold value for the CY 2024 performance period/2026 MIPS payment year.

TABLE 51: Possible Values for the CY 2024 Performance Period/2026 MIPS Payment Year Performance Threshold

2017 Performance Period	2018 Performance Period	2019 Performance Period	2020 Performance Period	2021 Performance Period	2017-2019 MIPS Performance Periods
74.65 Points	87.00 Points	85.63 Points	89.47 Points	89.22 Points	82.06 Points

As shown in Table 51, the mean final scores available for consideration for the CY 2024 performance period/2026 MIPS payment year performance threshold cover a range of values from 74.65 points to 89.47 points (rounded to 75 points and 89 points, respectively). We propose to use the CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years (mean of 82 points, rounded down from 82.06 points) as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year for several reasons.

First, as stated above in section IV.A.4.h.(2)(b) of this proposed rule, we believe using the mean or median of final scores across three performance periods would smooth out year-to-year fluctuations in the performance threshold, developing greater consistency and stability in MIPS, and providing more predictability for MIPS eligible clinicians who may wish to set MIPS performance goals. This would also allow us to include more scores in the computation of the mean or median, and therefore mitigate the impact of unusual fluctuations in performance specific to a 24-month or a 12-month timeframe. For example, since we applied extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) (85 FR 19277 through 19278) for the CY 2019 performance period/2021 MIPS payment year, we believe using the additional 24 months of data from the CY 2017 and 2018 performance periods/2019 and 2020 MIPS payment years will allow us to mitigate any potential impact of outliers in computing the mean to establish the performance threshold.

Second, we also believe continuing a gradual and incremental increase in the performance threshold by establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year at 82 will provide stability to MIPS eligible clinicians. This proposed performance threshold value would be an increase of nearly 7 points from the CY 2023 performance period/2025 MIPS payment year performance threshold of 75 points. This increase would be smaller than the 12-to-15-point increases in previous years, apart from the CY 2023 performance period/2025 MIPS payment year, during which the performance threshold remained the same as the previous year. We note that

the incremental and gradual increase is no longer required by section 1848(q)(6)(D)(iv) of the Act. However, we still believe that in the long term, the program is served by incremental and gradual changes, such as an increase in the performance threshold to best reflect MIPS eligible clinicians' recent performance by using data from later years. We also believe an incremental and gradual change in the performance threshold for the CY 2024 performance period/2026 MIPS payment year is appropriate as the PHE for COVID–19 concludes.

Finally, we also believe the performance threshold of 82 strikes an appropriate balance of using more robust data and yet accounting for clinician practices that are still recovering from the impacts of the COVID–19 PHE. If we were to use more recent data from CY 2018 performance period/2020 MIPS payment year or CY 2019 performance period/2021 MIPS payment year means, the increase would be more substantial than the incremental increase to 82.

The CY 2023 performance period/2025 MIPS payment year is the only year for which we did not increase the performance threshold from the prior year due to reasons noted in the CY 2023 PFS final rule (87 FR 70096 through 70100). First, we acknowledged that we removed transition policies, such as quality bonus points which had been established for scoring the quality performance category for the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years (86 FR 65491 through 65507). Second, we stated that, for the CY 2019 through 2021 performance periods/2021 through 2023 MIPS payment years, we applied certain extreme and uncontrollable circumstances policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide due to the COVID–19 PHE, which resulted in the reweighting of some performance categories if data were not submitted for a MIPS eligible clinician. Given the elimination of those transition policies, as well as the possibility the performance categories will not be reweighted for as many MIPS eligible clinicians for the CY 2023 performance period/2025 MIPS payment year, we expected the mean final score for CY 2023 performance period/2025 MIPS payment year to be lower than the mean final scores from the CY 2018 through 2020 performance periods/2020 through 2022 MIPS payment years. On these bases, we established the performance threshold at 75 for the CY 2023 performance period/2025 MIPS payment year, without any change from the prior year (87 FR 70096 through 70100).

However, for the CY 2024 performance period/2026 MIPS payment year, we no longer need to account for those reasons stated in CY 2023 PFS final rule (87 FR 70096 through 70100) and explained above, and therefore, believe it is appropriate to increase the performance threshold. For example, the COVID–19 PHE expired on May 11, 2023, emphasizing the less unpredictable impact of the COVID–19 PHE on health systems' expenditures and resources.[319] In addition, we no longer believe we need to consider MIPS transition policies because they are no longer in effect and clinicians have now had several years of experience in reporting within MIPS, which has been in effect for seven years. Finally, we believe that, as clinicians gain more experience within the MIPS program and as more recent data are available, we should incorporate more recent data in determining the performance threshold. We believe our proposal to use the mean of the final scores for the CY 2017 through 2019 performance periods/2019 through 2021 MIPS payment years as the prior period for the purpose of determining the performance threshold for the CY 2024 performance period/2026 MIPS payment year achieves an appropriate balance.

Under this proposal, and pursuant to the methodology we established previously at § 414.1405(g), the performance threshold for the CY 2024 performance period/2026 MIPS payment year would be the mean of the final scores for all MIPS eligible clinicians for the CY 2017 through 2019 performance periods/2019 through 2021 MIPS payment years, which is 82 points (rounded from 82.06 points). We are proposing corresponding changes to § 414.1405(b)(9) to reflect this proposal.

Alternatively, as an effort to use more recent data, we considered using the single 2019 performance period/2021 MIPS payment year, with a mean of 86 (rounded from 85.63) to establish the performance threshold for the CY 2024 performance period/2027 MIPS payment year. However, in efforts to use more robust data from a longer period of time, we are proposing using the CY 2017 through 2019 performance period/2019 through 2021 MIPS payment year as the prior period, with its mean of 82 points, to set the performance threshold for the CY 2024 performance period/2026 MIPS payment year. We also believe the performance threshold of 82 instead of 86 would be more appropriate for clinician practices that are still recovering from the impacts of the COVID–19 PHE.

In the Regulatory Impact Analysis (RIA) in section VII.E.23.d.(4) of this proposed rule, we estimate that approximately 46 percent of MIPS eligible clinicians would receive a negative payment adjustment for the CY 2024 performance period/2026 MIPS payment year if the policies proposed in this proposed rule are finalized and the performance threshold is equal to 82 points. We refer readers to the alternatives considered in the RIA in section VII.F.4 of this proposed rule where we present the impact of using data from alternative years to determine the performance threshold for the CY 2024 performance period/2026 MIPS payment year.

We are requesting comments on this proposal, as well as whether we should use means of final scores from alternative years to set the performance threshold for the CY 2024 performance period/2026 MIPS payment year, which we considered and discussed in the RIA in section VII.F.4 of this proposed rule.

(3) Example of Adjustment Factors

Figure 1 provides an illustrative example of how various final scores will be converted to a MIPS payment adjustment factor using the statutory formula and based on our proposed policies for the CY 2024 performance period/2026 MIPS payment year. In Figure 1, the performance threshold is set at 82 points, as we have proposed in section IV.A.4.h.(2)(c) of the proposed rule.

For purposes of determining the maximum and minimum range of potential MIPS payment adjustment factors, section 1848(q)(6)(B) of the Act defines the applicable percentage as 9 percent for the CY 2024 performance period/2026 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment.

However, there are two modifications to this linear sliding scale. First, as specified in section 1848(q)(6)(A)(iv)(II) of the Act, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and

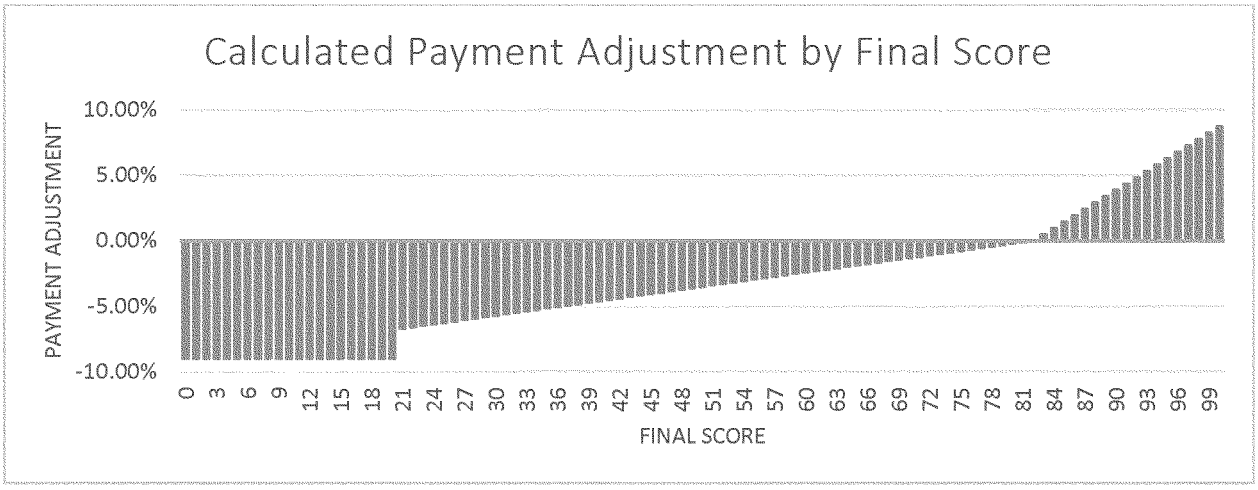
[319] *https://aspr.hhs.gov/legal/PHE/Pages/covid19-11Jan23.aspx; https://www.nytimes.com/2023/01/30/us/politics/biden-covid-public-health-emergency.html.*

20.5 points based on the performance threshold of 82 points for the CY 2024 performance period/2026 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive a negative MIPS payment adjustment factor equal to 9 percent (the applicable percentage). Second, the linear sliding scale for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0, as required by section 1848(q)(6)(F)(i) of the Act.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent (the applicable percentage). If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 82 points (the proposed performance threshold for the CY 2024 performance period/2026 MIPS payment year) would receive a neutral MIPS payment adjustment.

Beginning with the CY 2023 performance period/2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act is no longer available. For this reason, Figure 1 does not illustrate an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE 1: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold for the CY 2024 performance period/2026 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 52 illustrates the changes in payment adjustment based on the final policies from the CY 2023 PFS final rule (87 FR 70096 through 70103) for the CY 2023 performance period/2025 MIPS payment year and the proposed policies for the CY 2024 performance period/2026 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 52: Illustration of Point System and Associated Adjustments Comparison between the CY 2023 Performance Period/2025 MIPS Payment Year and the Proposed CY 2024 Performance Period/2026 MIPS Payment Year

2023 Performance Period		2024 Performance Period	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
0.0-18.75	Negative 9%	0.0-20.5	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	20.51-81.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.0	0% adjustment	82.0	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	82.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 86.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

g. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

We made performance feedback available for the CY 2019 performance period/2021 MIPS payment year on August 5, 2020; for the CY 2020 performance period/2022 MIPS payment year on August 2 and September 27, 2021; and for the CY 2021 performance period/2023 MIPS payment year on August 22, 2022. Although we aim to provide feedback for the CY 2022 performance period/2024 MIPS payment year on or around July 1, 2023, it is possible the release date could be later depending on circumstances. We direct readers to *qpp.cms.gov* for more information.

K. Targeted Review

a. Background

Section 1848(q)(13)(A) of the Act requires that the Secretary establish a process under which a MIPS eligible clinician may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to the MIPS eligible clinician. In the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358), we finalized a targeted review process and related requirements under MIPS wherein a MIPS eligible clinician or group may request a review of the calculation of the MIPS payment adjustment factor and, as applicable, the calculation of the additional MIPS payment adjustment factor applicable to such MIPS eligible clinician or group for a year. Currently, MIPS eligible clinicians, groups, and Alternative Payment Model (APM) entities may request and receive targeted review of our calculation of their MIPS payment adjustment factor(s) under our established process and related requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77546), we codified the MIPS targeted review process and related requirements at § 414.1385(a).

In the CY 2020 PFS final rule (84 FR 63045 through 63049), we revised the MIPS targeted review process and related requirements to address persons eligible to request targeted review, timeline for submission of targeted review requests, denial of targeted review requests, our requests for additional information, notification of targeted review decisions, and scoring recalculations. We codified these revisions to the targeted review process and related requirements at § 414.1385(a) (84 FR 63197 through 63198).

Currently, as specified at § 414.1385(a)(2), we provide that all requests for targeted review must be submitted within a 60-day period, beginning on the day that we make available the MIPS payment adjustment factors for the MIPS payment year applicable to each MIPS eligible clinician. In addition, § 414.1385(a)(2) provides that we may extend the targeted review request submission period. However, this current submission period for MIPS targeted review presents significant challenges to CMS as we seek to implement application of a differentially higher PFS conversion factor for eligible clinicians who are Qualifying APM Participants (QPs) for a year beginning with the CY 2024 QP Performance period/2026 payment year, as required by section 1848(d)(1)(A) of the Act.

Specifically, to ensure application of the alternative conversion factor for eligible clinicians who are QPs, we must submit the final list of QPs to our Medicare Administrative Contractors no later than October 1st of the preceding year. However, under our current

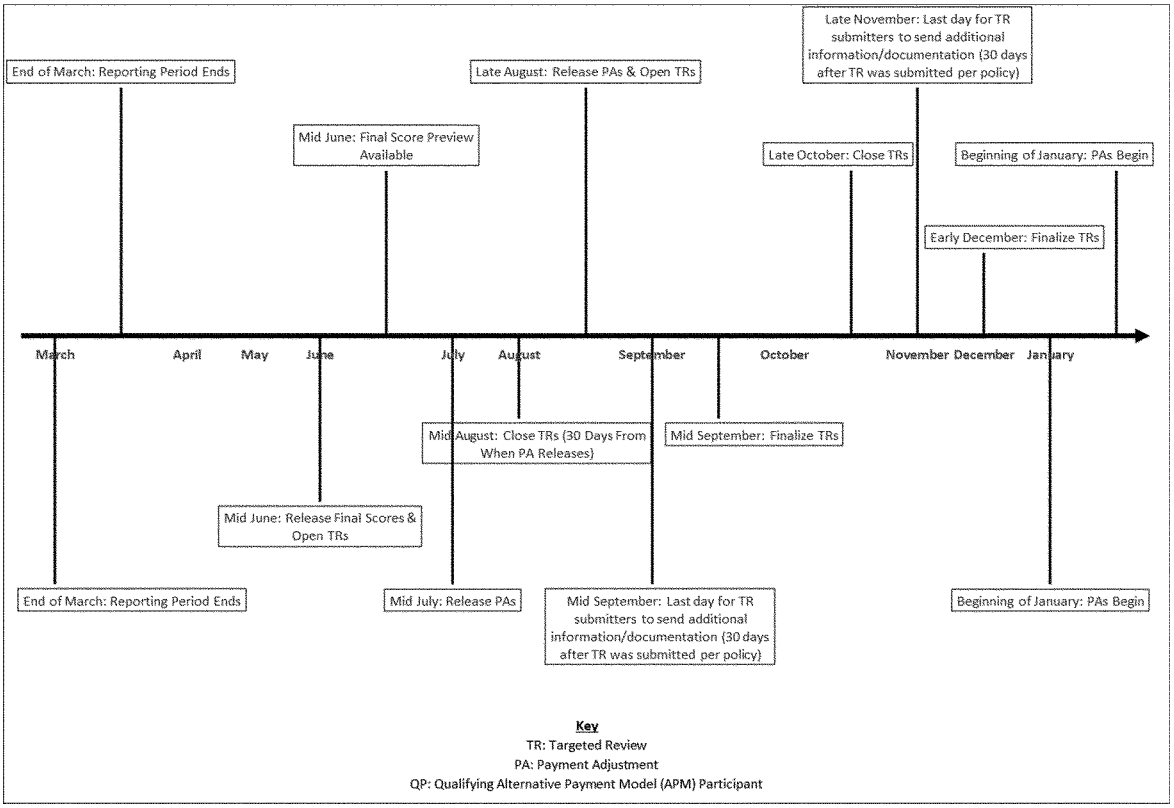
targeted review timeline for MIPS, this information would not be available until the first week of December. This is because the targeted review request submission period begins upon notification of the MIPS payment adjustment factors, which takes place sometime in August, and ends 60 days later, sometime in November. While QPs are excluded from MIPS reporting and any MIPS payment adjustment, we have received and addressed several requests for targeted review based on a clinician disputing whether they should be designated as a QP or a MIPS eligible clinician for purposes of payment under the Quality Payment Program. Based on our experience, we have found that more often than not a MIPS eligible clinician was initially identified as a QP but did not in fact participate in an Advanced APM and, conversely, a MIPS eligible clinician who believes they had achieved QP status was not identified as such. The targeted review process allows for clinicians to bring these issues to our attention. Accordingly, the targeted review process is essential to compiling an accurate list of QPs, which is necessary for purposes of determining who receives the application of the higher PFS conversion factor (also known as ''qualifying APM conversion factor'') of 0.75 percent (versus non-QPs, who receive 0.25 percent).

Section 1848(q)(13)(A) of the Act does not specify a timeframe for targeted review, broadly requiring that we ''establish a process'' for informal review of our calculation of the MIPS adjustment factor. Section 1848(q)(13)(A) of the Act only requires that the targeted review process permit a MIPS eligible clinician to seek ''informal review of the calculation of the MIPS adjustment factor (or factors)'' applicable to the MIPS eligible clinician for a MIPS payment year. We believe this broad authority for establishing this targeted review process, and lack of specificity as to any timeframe required for such process, permits CMS to determine a reasonable time period for submission of a request for targeted review so long as a MIPS eligible clinician can submit a request after we have informed them of our calculation of their MIPS adjustment factor(s).

Therefore, we are proposing to permit submission of a request for targeted review beginning on the day we make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. This proposal will allow for a total of approximately 60 days for the targeted review submission period (approximately 30 days before publication of the MIPS payment adjustments factors and 30 days thereafter). We believe this proposal will provide us with the necessary time to adjudicate the targeted reviews and finalize the QP status list by October 1st. If finalized, we are proposing to codify this proposed modification to this policy at § 414.1385(a)(2).

In Figure 2, we illustrate our proposed change to the timeline of the targeted review. The text above the timeline reflects the current process for targeted review while the text below the timeline reflects the proposed process in Figure 2.

FIGURE 2: Current and Proposed Targeted Review Process



To further shorten the timeline of the targeted review process for the reasons discussed above, we also are proposing to amend § 414.1385(a)(5). Specifically, we are proposing to require that, if CMS requests additional information under the targeted review process, that that additional information must be provided to and received by CMS

within 15 days of receipt of such request. This proposal would modify the current timeline to respond to CMS' request set forth at § 414.1385(a)(5), which is within 30 days of receipt.

In the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358), we implemented a virtual groups participation option under MIPS. Since virtual groups are eligible to submit data to the MIPS program, we are proposing to add virtual groups as being eligible to submit a request for targeted review. Finally, as discussed in section IV.A.4.d (4) of this proposed rule, we are also proposing to add subgroups as being eligible to submit a request for targeted review. We are proposing to codify these additions at § 414.1385(a).

We invite public comment on these proposals.

k. Third Party Intermediaries General Requirements

(1) Codification of Previously Finalized Policy From Preamble

A third party intermediary is an entity that CMS has approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for one or more of the quality, improvement activities, and Promoting Interoperability performance categories (§ 414.1305). Many of the policies that apply to third party intermediaries were finalized through prior rulemaking but not codified in the CFR. Among other things, this has made it challenging for third party intermediaries to track certain program requirements and has caused confusion for MIPS participants and third party intermediaries.

We have reviewed the previously finalized language and identified policies that we believe should be codified for these reasons. We describe these proposals and provide background throughout this section.

(2) General Requirements

(a) Background

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84926 through 84947), the CY 2022 PFS final rule (86 FR 65538 through 65550), and the CY 2023 PFS final rule (87 70102 FR through 70109) for our previously established policies regarding third party intermediaries. Where we are proposing to codify existing final policy, we incorporate the rationale described in these prior rules by reference.

In this proposed rule, in addition to codifying previously finalized policies and making technical updates for clarity, we propose to: (1) Add requirements for third party intermediaries to obtain documentation; (2) Specify the use of a simplified self-nomination process for existing qualified clinical data registries (QCDRs) and qualified registries; (3) Add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (4) Add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (5) Modify requirements for QCDRs and qualified registries to support MVP reporting; (6) Specify requirements for a transition plan for QCDRs and qualified registries; (7) Specify requirements for data validation audits; (8) Add additional criteria for rejecting QCDR measures; (9) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) Eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify the process for publicly posting remedial action; and (14) Specify the criteria for audits.

(b) Requirement To Obtain Documentation

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 and 77385), we established requirements that QCDRs and qualified registries obtain signed documentation from clinicians and groups regarding their authority to handle and submit data on the clinician and group's behalf. We established that QCDRs and qualified registries must enter into appropriate Business Associate Agreements with MIPS eligible clinicians. QCDRs and qualified registries must obtain signed documentation that each holder of a national provider identifier (NPI) has authorized the third party intermediary to submit ''quality measure results, improvement activities measure and activity results, advancing care information objective results and numerator and denominator data or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation.'' The documentation should be annually obtained at the time the clinician or group enters into an agreement with the QCDR or qualified registry for the submission of MIPS data to the QCDR or qualified registry. A group, subgroup, Virtual Group, or APM Entity may have their authorized representative give permission to the third party intermediary to submit their data. Additionally, in the CY 2018 Quality Payment Program final rule (82 FR 53812), we clarified that Business Associate Agreements must comply with the HIPAA Privacy and Security Rules. Records of the authorization must be maintained for 6 years after the performance period ends (81 FR 77370). We propose to codify these requirements at § 414.1400(b)(3)(xii) and (xiii).

We invite comments on this proposal.

(c) Requirement To Report in Form and Manner Specified

(i) Criteria for Data Submission

At § 414.1400(a)(2)(C), we require that all data submitted by a third party intermediary must be submitted in the form and manner specified by CMS. We are specifying that these requirements include the obligation for a third party intermediary to: (1) report the number of eligible instances (reporting denominator); (2) report the number of instances a quality service is performed (performance numerator); (3) report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification; (4) comply with a CMS-specified secure method for data submission, such as submitting the QCDR's data in an XML file; (5) be able to calculate and submit measure-level reporting rates or the data elements needed to calculate the reporting and performance rates by taxpayer identification number (TIN)/NPI and/or TIN; (6) be able to calculate and submit a performance rate (that is the percentage of a defined population who receive a particular process of care or achieves a particular outcome based on a calculation of the measures' numerator and denominator specifications) for each measure on which the TIN/NPI or TIN reports; (7) provide the performance period start date the QCDR will cover; (8) provide the performance period end date the QCDR will cover; (9) report the number of reported instances, performance not met, meaning the quality actions was not performed for no valid reason as defined by the measure specification; and (10) submit quality, advancing care information, or improvement activities data and results

to us in the applicable MIPS performance categories for which the QCDR is providing data (81 FR 77367 through 77369 and 77384 through 77385). These criteria for data submission are technical requirements of functioning QCDRs and qualified registries.

(ii) Reporting on All Patients, Including Non-Medicare Patients

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries are required to submit data on all patients, not just Medicare patients. In section IV.A.4.f.(1)(b) of this rule, we propose a revision to the definition of the term collection type to allow Shared Saving Program ACOs meeting the reporting requirements under the APP to report on a subset of patients that is partially defined by having the payer of Medicare. We propose to codify our previously established requirement that data submitted by third party intermediaries must include data on all of the MIPS eligible clinician's patients regardless of payer, with the addition of the phrase ''unless otherwise specified by the collection type'' at § 414.1400(a)(3)(ii)(A). We invite comments on this proposal.

(3) Requirements for QCDRs and Qualified Registries

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(B)(ii) of the Act provides that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of certified EHR technology (CEHRT) and qualified clinical data registries.

We refer readers to § 414.1400(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77374 and 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 and 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944), the CY 2022 PFS final rule (86 FR 65540 through 65550) and the CY 2023 PFS final rule (87 FR 70103 through 70106) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

As described at § 414.1305, a qualified registry is a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS.

We refer readers to § 414.1400(b), the CY 2017 Quality Payment Program final rule (81 FR 77382 and 77386), the CY 2018 Quality Payment Program final rule (82 FR 53815 and 53818), the CY 2019 PFS final rule (83 FR 59906), the CY 2020 PFS final rule (84 FR 63074 through 63077), the CY 2021 PFS final rule (85 FR 84944 through 84947), and the CY 2022 PFS final rule (86 FR 65539 through 65548) for previously finalized standards and criteria for qualified registries.

(b) Self-Nomination and Program Requirements

(i) Subgroup Reporting

In the CY 2022 Quality Payment Program final rule (86 FR 65544), we established the requirement that third party intermediaries must support subgroup reporting beginning with the CY 2023 performance period/2025 MIPS payment year. This requirement that third party intermediaries support subgroup reporting was finalized because it would allow for clinicians to meaningfully report MIPS Value Pathways (MVPs) given that subgroups will be implemented concurrently with MVPs. We propose to add new language to codify this policy. We propose to revise § 414.1400(b)(1)(iii) that beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support subgroup reporting.

We invite comments on this proposal.

(ii) Simplified Self-Nomination Process for Existing QCDRs and Qualified Registries in MIPS, That Are in Good Standing

In the CY 2018 Quality Payment Program final rule (82 FR 53811 through 53812 and 53817 through 53818), we established that beginning with the CY 2019 performance period/2021 MIPS payment year, QCDRs and qualified registries in good standing (that is, QCDRs and qualified registries that are not on probation or disqualified) (81 FR 77386 through 77389) that ''wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable'' (see also § 414.1400(b)(2)). When this is the case, third party intermediaries may use the simplified process. The goal of the simplified self-nomination form is to reduce the self-nomination burden for third party intermediaries in good standing by allowing them to self-nominate with a mostly pre-populated self-nomination form. The policy allows third party intermediaries to attest that sections of their application have no changes even if there are minimal changes or substantive changes in other parts of their application. An example of a minimal change is adding or removing MIPS quality measures. An example of a substantive change is new QCDR measures for consideration. For sections of an application that do require changes, the requirements are the same as those for the normal self-nomination process (82 FR 53808).

In the course of implementing this policy, we have learned that the text of § 414.1400(b)(2) has confused some third party intermediaries such that they have attested that their previously approved self-nomination form is still accurate and have not submitted self-nomination forms because they thought they did not need to do so if they had no changes. We are proposing to revise § 414.1400(b)(2) to reflect that QCDRs and qualified registries are still required to submit their self-nomination form even if they utilize the simplified self-nomination process. Even if a third party intermediary has no change to make to its form from the previous year, there may be new sections to fill out and they need to respond to attestations within the course of the application. We propose to revise the last sentence of § 414.1400(b)(2) from ''For the CY 2019 performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period'' to state, ''For the CY 2019 performance period/2021 MIPS payment year and future years, an existing QCDR or qualified registry that is in good standing may use the simplified self-nomination process during the self-nomination period, from

July 1 and September 1 of the CY preceding the applicable performance period.'' This proposal would ensure that third party intermediaries that have previously participated in MIPS and are in good standing can use the process to reduce the burden of self-nomination.

We invite comments on this proposal.

(iii) Measure Numbers and Identifiers and Titles for the Improvement Activity Performance Category, the Promoting Interoperability Performance Category, and MVPs

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must provide the measure numbers for the MIPS quality measures on which the QCDR and qualified registry is reporting. We propose to codify this previously finalized provision at § 414.1400(b)(3)(ix). For completion and consistency, we also need to receive identifiers for improvement activities, Promoting Interoperability, and titles for MVPs. This information is used to track which quality measures, improvement activities, Promoting Interoperability performance category measures and MVPs QCDRs and qualified registries support in a performance period. This information is available on the qualified postings that are published on the QPP Resource Library. We propose that § 414.1400(b)(3)(ix) would additionally require QCDRs and qualified registries to submit to CMS the identifiers for the improvement activity performance category, the Promoting Interoperability performance category measures, and titles for MVPs.

We invite comments on this proposal.

(iv) Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that one criterion for data submission for QCDRs and qualified registries is that they must be able to submit results to CMS for at least six individual quality measures with at least one outcome measure during self-nomination. If an outcome measure is not available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure. We propose to codify this previously finalized provision at § 414.1400(b)(3)(x).

We invite comments on this proposal.

(v) Qualified Posting Attestation

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must sign a document that verifies their ''name, contact information, cost for MIPS eligible clinicians or groups to use the qualified registry, services provided, and the specialty-specific measure sets the qualified registry intends to report.'' As technology has progressed, we no longer need third party intermediaries to sign a document and instead require an attestation. We became aware that this requirement is not consistent with our established policy in describing the manner in which the QCDR or qualified registry documents this information. In order to align with current processes, we propose to add § 414.1400(b)(3)(xiv), which would require that QCDRs and qualified registries attest that the information listed on the qualified posting is accurate. The qualified posting contains information to help clinicians, groups, subgroups, virtual groups, APM Entities determine the services, cost, reporting options, measures/activities, etc. that a CMS-approved intermediary supports. We publish it every performance period and update it, as needed. While we have used the term qualified posting since the inception of the Quality Payment Program, we have not previously defined this term, and therefore, we propose to define qualified posting as the document made available by CMS that lists QCDRs or qualified registries available for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities at § 414.1305.

We invite comments on these proposals.

(vi) Data Access Capabilities

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must comply with any request by CMS to review data submitted by a third party intermediary for purposes of MIPS. We propose to codify this previously finalized provision at § 414.1400(b)(3)(xv).

We invite comments on this proposal.

(vii) Attestation of Data Access Capabilities

As was previously described, the CY 2017 Quality Payment Program rule finalized the requirement for third party intermediaries to comply with any request by CMS to review data submitted by a third party intermediary for purposes of MIPS reporting requirements (81 FR 77367 through 77369 and 77384 through 77385). However, it did not require third party intermediaries to attest to their capabilities. Attestation during the self-nomination period emphasizes the importance of this capability for third party intermediaries even if the capability is not ultimately utilized later. We propose to add § 414.1400(b)(3)(xvi)(A) to require that a QCDR or a qualified registry attest that it has required each MIPS eligible clinician on whose behalf it reports to provide the QCDR or qualified registry with all documentation necessary to verify the accuracy of the data on quality measures that the eligible clinician submitted to the QCDR or qualified registry. We also propose to add § 414.1400(b)(3)(xvi)(B) to require that a QCDR or a qualified registry must attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in § 414.1400(b)(3)(xvi)(A) to CMS upon request to ensure that data can be accessed by the third party intermediary for auditing purposes as we have heard from some third party intermediaries that they do not have access to the data and depend on clinicians do the audit.

We invite comments on this proposal.

(viii) Third Party Intermediary Support of MVPs

In the CY 2022 PFS final rule (86 FR 65543), we finalized a new requirement at § 414.1400(b)(1)(ii) that, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. This proposal was finalized because MVPs are beginning to be implemented in the CY 2023 performance period/2025 MIPS payment year, and third party intermediaries have the necessary experience reporting data to support MVP reporting.

To further clarify this finalized policy, we responded to a comment in the CY 2022 PFS final rule (86 FR 65543) by explaining that third party intermediaries who support MVPs are required to ''support all measures and activities available in the MVP across the quality, improvement activities, and Promoting Interoperability performance categories. The exceptions to this requirement are the cost measures and population health measures . . . [and] QCDR measures, which are only reportable through a QCDR. In instances where QCDR measures are included in an MVP, a qualified registry or health IT vendor will be expected to support all other quality measures included within the MVP.'' Some interested parties have

expressed concern regarding this requirement as many MVPs include measures that may be reported by clinicians across multiple specialties, some of whom might be outside their intended customer base. We are concerned that continuing this strict requirement for MVP support could undermine adoption during the time in which MVP submission is an option under MIPS. Given that many third party intermediaries may not support measures for clinicians in all specialty areas that might report a MVP, we are proposing to add a sentence at the end of § 414.1400(b)(1)(ii) that a QCDR or a qualified registry is required to support MVPs pertinent to the specialties they support. The proposed addition states that a QCDRs or a qualified registry must support all measures and improvement activities available in the MVP with two exceptions. The first proposed exception to this requirement at § 414.1400(b)(1)(ii)(A) is that if an MVP includes several specialties, then a QCDR or a qualified registry is only expected to support the measures that are pertinent to the specialty of their clinicians. For example, if an orthopedic care MVP includes both surgery and physical therapy measures, and the third party intermediary caters specifically to physical therapists, they are not required to support the surgical measures. The second proposed exception at § 414.1400(b)(1)(ii)(B) is that QCDR measures are only required to be reported by the QCDR measure owner. In instances where a QCDR does not own the QCDR measures in the MVP, the QCDR may only support the QCDR measures if they have the appropriate permissions.

We invite comments on these proposals.

(ix) Readiness To Accept Data

In the CY 2019 PFS final rule (83 FR 59761), we established that a QCDR or a qualified registry must be up and running by January 1st of the performance period so that they can accept and retain clinician data starting on January 1st. We propose to codify at § 414.1400(b)(3)(xvii) the requirement that a QCDR or a qualified registry must be able to accept and retain data by January 1 of the applicable performance period.

We invite comments on this proposal.

(x) Duration of Services Provided

In the CY 2020 PFS final rule (84 FR 63053), we finalized a new requirement at § 414.1400(a)(2)(i)(E) that the organization must provide services throughout the entire performance period and applicable data submission period. In section IV.A.4.k.(3)(b)(xi) of this rule, we discuss the requirements for a transition plan for cases in which organizations are not able to provide services throughout the entire year. While we recognize and allow for cases in which organizations may find themselves unable to provide services throughout the course of an entire year, we would require that they indicate their intent to do so as part of program requirements. We propose to modify this requirement to state the organization must certify it intends to provide services throughout the entire performance period and applicable data submission period. We propose to make this change at § 414.1400(a)(2)(i)(C) as a result of our proposal to divide requirements for self-nomination from programmatic requirements as discussed in section IV.A.4.k.(7) of this rule.

We invite comments on these proposals.

(xi) Transition Plan Requirements

In the CY 2020 PFS final rule (84 FR 63052 through 63053), we finalized a new requirement at § 414.1400(a)(2)(i)(F) that prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan. As part of an overall effort to divide self-nomination requirements from program requirements as discussed in section IV.A.4.k.(7) of this rule, at § 414.1400, we propose to redesignate and revise paragraph (a)(2)(i)(F) to paragraph (a)(3)(iv) that, prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan by a date specified by CMS. The transition plan must address the following issues, unless different or additional information is specified by CMS. We propose to specify the contents required in the transition plan in paragraphs (a)(3)(iv)(A) through (E). Therefore, we propose to add § 414.1400(a)(3)(iv)(A) to require that the transition plan state the issues that contributed to the withdrawal mid-performance period or discontinuation of services mid-performance period. We also propose to add § 414.1400(a)(3)(iv)(B), which would require that the transition plan state the number of clinicians, groups, virtual groups, subgroups or APM entities inclusive of MIPS eligible, opt-in and voluntary participants that would need to find another way to report and as applicable, and identify any QCDRs that were granted licenses to QCDR measures which would no longer be available for reporting due to the transition. We further propose to add paragraph (a)(3)(iv)(C) to state the steps the third party intermediary will take to ensure that the clinicians, groups, virtual groups, subgroups, or APM Entities identified in § 414.1400(a)(3)(iv)(B)(*1*) are notified of the transition in a timely manner and successfully transitioned to an alternate third party intermediary, submitter type, or, for any measure or activity on which data has been collected, collection type, as applicable. At paragraph (a)(3)(iv)(D), we propose to require that the transition plan include a detailed timeline of when the third party intermediary will take the steps identified in paragraph (a)(3)(iv)(C), including notification of affected clinicians, groups, virtual groups, subgroups, or APM Entities, the start of the transition, and the completion of the transition. Finally, we propose to add at paragraph (a)(3)(iv)(E) that the third party intermediary must communicate to CMS that the transition was completed by the date included in the detailed timeline. The proposals would enable CMS to have documentation of the steps, actions, tasks, and timeline for completion of the transition of clients.

We invite comments on these proposals.

(c) Submission Requirements

(i) Risk-Adjusted Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77384 through 77385), we established that qualified registries ''submitting MIPS quality measures that are risk-adjusted . . . must submit the risk-adjusted measure results to CMS when submitting the data for these measures.'' We propose to codify this previously finalized provision at § 414.1400(b)(3)(xi).

We invite comments on this proposal.

(ii) Data Validation Audit Requirements

Section 414.1400(b)(3)(v) outlines the requirements for third party intermediary's annual data validation audits. As specified at paragraph (b)(3)(v)(E), the QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements: (1) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR or qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR or qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR or qualified registry may use a sample size of 50 TIN/NPIs. (2) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients. We finalized this policy (81 FR 77366 through 77367) to reflect the number of reporting entities, which may be individuals, as represented by TIN/NPIs, but are often compositions of TIN/NPIs as represented by groups, subgroups, or APM entities. Since these compositions represent a single unit of measurement, we believe that they should be considered as a single unit.

We have received questions about the required sampling methodology from interested parties who are confused by the references to TIN/NPI in the context of sample size and how they map to individual MIPS eligible clinicians, groups, virtual groups, subgroups or APM Entities. To reduce confusion among third party intermediaries regarding the data validation audit sample, we propose to revise § 414.1400(b)(3)(v)(E)(*1*) and (*2*) to replace references to TIN/NPI with ''a combination of individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM Entities.'' The new text would state: (1) Uses a sample size of at least 3 percent of a combination of individual clinicians, groups, virtual groups, subgroups and APM Entities for which the QCDR or qualified registry will submit data to CMS, except that if the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM Entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM Entities, the QCDR or qualified registry may use a sample size of a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM Entities; and (2) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM Entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM Entity must include a minimum of 5 patients and need not include more than 50 patients.

We invite comments on this proposal.

(4) Requirements Specific to QCDRs

(a) Background

As described at § 414.1305, a QCDR is an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Section 1848(q)(5)(ii)(B) of the Act provides that the Secretary shall encourage MIPS eligible professionals to report on applicable measures through the use of CEHRT and qualified clinical data registries.

We refer readers to § 414.1400(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77374 and 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 and 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84937 through 84944), the CY 2022 PFS final rule (86 FR 65540 through 65550) and the CY 2023 PFS final rule (87 FR 70103 through 70106) for previously finalized standards and criteria for QCDRs and QCDR measure requirements.

(b) QCDR Measure Self-Nomination Requirements

(i) New QCDR Measures May Not Be Submitted After Self-Nomination

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77377), we established that QCDRs could submit measures that are not on the annual list of MIPS quality measures as part of the self-nomination process for an entity to become a QCDR. In the CY 2018 Quality Payment Program final rule (82 FR 53808), we established a process by which existing QCDRs that are in good standing could attest that certain aspects of their previous year's approved self-nomination have not changed. We intended for the self-nomination document to be comprehensive in terms of which QCDR measures would be submitted for consideration. However, we have received requests to add measures following the completion of the QCDR self-nomination process for the performance year. Our review process requires consideration of a complete self-nomination with all measures, so we propose to add that the measure was submitted after self-nomination to our list of reasons for rejecting a QCDR measure at § 414.1400(b)(4)(iv)(O).

We invite comments on this proposal.

(ii) Limitations on Number of QCDR Measures Submitted for Self-Nomination

In the CY 2017 Quality Payment Program final rule, we established at § 414.1400(b)(4)(i) that QCDRs must submit certain specifications for QCDR measures that would be considered for approval by CMS (81 FR 77374 through 77378). These measures would then be considered for approval or rejection under the requirements of § 414.1400(b)(4)(iii) and (iv). CMS reviews these measures carefully and each additional measure takes considerable time and effort to review. We have had experiences in which a single QCDR has submitted a large number of QCDR measures for consideration. While we are mindful that there may be a number of valid measure concepts, we are generally trying to focus measurement within the Quality Payment Program. In an effort to optimize resource allocation and encourage QCDRs to focus their submitted measures on those that have the highest value, we are proposing to add at § 414.1400(b)(4)(iv)(P) that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration. We considered a lower limit given that clinicians in traditional MIPS are only required to report on 6 quality measures and clinicians reporting via MVPs may report even fewer. However, we recognize that some QCDRs serve more diverse clinical populations and could conceivably wish to submit this many as part of self-nominations. We note that we would continue to evaluate individual measures on their merits as specified in our requirements at § 414.1400(b)(4)(iii) and (iv).

We invite comments on this proposal.

(iii) Requirements for Previous Data on QCDR Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77368), we established a requirement that for non-MIPS measures the QCDR must provide us, if available, data from years prior to the start of the performance period. We

propose to codify this previously finalized provision at § 414.1400(b)(4)(i)(C).

We invite comments on this proposal.

(iv) Requirement for QCDR Measure Specifications To Remain Published Through the Performance Period and Data Submission Period

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77376), we established at § 414.1400(b)(4)(i)(B) that no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the QDCR must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. While we established when this posting was required, we did not establish a standard for the duration of this posting. We have become aware of situations in which QCDR measure owners have removed this documentation during the course of the performance period or before the closure of the submission period. We propose to revise § 414.1400(b)(4)(i)(B) to add a provision that the approved QCDR measure specifications must remain published through the performance period and data submission period. Although it was not previously specified, it was our intention that this information be made available for the entirety of the time that the measure could be considered and reported by clinicians or groups as part of the Quality Payment Program. Measure specifications must be available throughout the duration of measure use for interested parties to understand the target population of the measure, how the measure is built and calculated, and to identify existing measure gaps. Clinicians may elect to begin collecting data at various times in the year and even if data collection has started, may need to consult specifications throughout the performance period to confirm that data collection is in concordance with the specifications. We believe this addition will prevent QCDRs from removing specifications following the initial required posting and increase transparency for participants. We also propose to make a technical update to the language removing the reference to providing the NQF number due to changes in the contractor that CMS uses for measure endorsement.

We invite comments on this proposal.

(5) Health IT Vendors

(a) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we established the category of health IT vendor in the Quality Payment Program, along with requirements for data submission. In the CY 2019 PFS final rule, we codified the definition of a health IT vendor as an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT) (83 FR 59907). In the CY 2022 PFS final rule (86 FR 65541), we finalized a reorganization of the regulatory text governing the third party intermediary section to improve clarity and readability. In that revised text, we established general requirements at § 414.1400(a), additional requirements for QCDRs and qualified registries at § 414.1400(b), and additional requirements for health IT vendors at § 414.1400(c).

(b) Proposal To Remove Health IT Vendor Category

In the CY 2021 PFS final rule, we established additional program safeguards regarding data validation audit and targeted audit requirements that would apply specifically to QCDRs and qualified registries. We noted (85 FR 84928 and 84929) that while we did not propose these additional requirements for health IT vendors, we had become aware of situations in which health IT vendors have submitted data that are inaccurate and unusable and that could result in improper payments or otherwise undercut the integrity of the MIPS program. In our review of comments in response to our solicitation on the future application of such requirements on health IT vendors, we observed that several commenters supported requirements for health IT vendors to perform data validation to align requirements with QCDRs and qualified registries and improve data integrity. We also observed that several commenters opposed additional data validation requirements for health IT vendors due to the associated cost, and that such a requirement would be duplicative of requirements of health IT vendors under the ONC regulatory framework.

Since the publication of the CY 2021 PFS final rule, we continue to have experiences with third party intermediaries submitting data that is inaccurate and unusable. We believe this necessitates a reconsideration of the lack of data validation requirements for health IT vendors in contrast to those requirements for QCDRs and qualified registries.

In the CY 2019 PFS final rule (83 FR 59747 through 59749), we established the definition of collection type, submitter type, and submission type. These definitions are intended to more precisely describe how data is collected and submitted for the Quality Payment Program. For the quality, Promoting Interoperability, and improvement activity performance categories, an approved third party intermediary may submit directly to the submissions application programming interface (API), or upload files via *qpp.cms.gov*. Historically, third party intermediaries are able to receive tokens by virtue of successful self-nomination as a QCDR or qualified registry or, for those technologies that use CEHRT, through a request to CMS.

In examining the different requirements for QCDRs and qualified registries and health IT vendors, we note that the primary difference is the requirement for self-nomination at § 414.1400(b)(2) and requirements primarily related to data validation audits at § 414.1400(b)(3). We considered whether we should add a self-nomination requirement for health IT vendors or require data validation audits for health IT vendors or both. However, we believe that adding a self-nomination requirement or data validation audit requirements would essentially eliminate the difference between a health IT vendor and a qualified registry. We observe today that many vendors serve in capacities as qualified registries, QCDRs or health IT vendors with similar technology. Rather than establish identical or nearly identical requirements for different categories of vendors, we instead propose to eliminate the health IT vendor category beginning with the CY 2025 performance period and by revising § 414.1400(a)(1)(iii). Absent a self-nomination process for Health IT vendors, we do not believe we can establish a meaningful enforcement mechanism to ensure that the vendors are meeting the requirements as we have laid out.

Removing Health IT vendors from the definition of third party intermediary will not preclude the vendors from assisting MIPS eligible clinicians with reporting under the program. Instead, the vendors may still provide their technology for clinicians to directly report under MIPS. We believe that eliminating the category of Health IT vendor as a distinct type of third party intermediary will create a clearer distinction between those vendors that are submitting data to us for the

purposes of MIPS and must meet the requirements of a qualified registry or QCDR and those vendors that work with clinicians through the sale and support of health IT that permits the clinician or group to submit the data.

We invite comments on this proposal.

(6) Remedial Action and Termination of Third Party Intermediaries

(a) Background

We refer readers to § 414.1400(e), the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77389), the CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), the CY 2021 PFS final rule (85 FR 84947), the CY 2022 PFS final rule (86 FR 65542 and 65550) and the CY 2023 PFS final rule (87 FR 70106 through 70109) for previously finalized policies for remedial action and termination of third party intermediaries.

(b) Additional Basis for Remedial Action

(i) Failure To Maintain Correct Contact Information

In the CY 2017 Quality Payment Program final rule, we established the process for self-nomination for QCDRs (81 FR 77364 through 77367) and qualified registries (81 FR 77383 through 77384). We also established the process for corrective action plans in the CY 2017 Quality Payment Program final rule (81 FR 77389). In our work with QCDRs and qualified registries, we experienced times when the QCDR or qualified registry did not respond to certain requests in a timely manner, thereby delaying program operations. In some cases, we had further correspondence with the QCDR or qualified registry and those organizations suggested that the contact information (generally an email address) submitted as part of the self-nomination was not correct, so the request was never received. While we understand that personnel can change over time in an organization, such a change does not relieve the QCDR or qualified registry of its obligations under these rules. Therefore, we propose an additional provision at § 414.1400(e)(2)(iv) to allow us to immediately or with advance notice terminate a third party intermediary that has not maintained current contact information for correspondence.

We invite comments on this proposal.

(ii) Consecutive Years on Remedial Action

In the CY 2017 Quality Payment Program final rule, we established a process for placing third party intermediaries on probation for not meeting requirements (81 FR 77387). Specifically, if a third party intermediary did not meet requirements for qualification, they could be placed on probation for the current performance period and/or the following performance period. We also established that after two years on probation, a third party intermediary would be disqualified for the subsequent performance year (81 FR 77387 through 77389). In the CY 2019 PFS final rule, policies relating to probation and disqualification were renamed and reorganized under remedial action and termination of third party intermediaries (83 FR 59908 through 59910). Additionally, we finalized reasons for terminating third party intermediaries including being placed on remedial action, not submitting a corrective action plan, and not promptly correcting data errors (83 FR 59908 through 59910). At that time, we did not propose any actions related to third party intermediaries on remedial action for multiple years, as had been established under our initial probation policy.

We continue to experience issues with third party intermediaries that require corrective action plans in multiple years. We believe that third party intermediaries that consistently require corrective action plans, whether for the same or unrelated issues, do not further the goals of the Quality Payment Program, which are to improve quality of care while limiting administrative burden. We believe allowing third party intermediaries that have consistently demonstrated failure to comply with CMS requirements such that they required corrective action plans undermine clinicians' and groups' efforts to improve quality and could result in increased administrative burden for those clinicians and groups. For this reason, we propose to add at § 414.1400(e)(2)(v) that CMS may terminate third party intermediaries that are on remedial action for 2 consecutive years. This proposal will minimize risk within the Quality Payment Program by terminating third party intermediaries that are consistently deemed as non-compliant.

We invite comments on this proposal.

(c) Revised Corrective Action Plan Requirements

As described in § 414.1400(e)(1)(i), among the remedial actions that CMS may take against a non-compliant third party intermediary is a corrective action plan (CAP). Under paragraphs (e)(1)(i)(A) through (D), unless different or additional information is specified by CMS, the CAP must address the following issues: (A) the issues that contributed to the non-compliance; (B) the impact to individual clinicians, groups, virtual groups, subgroups, or APM Entities, regardless of whether they are participating in the program because they are MIPS eligible, voluntarily participating, or opting in to participating in the MIPS program; (C) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future; and (D) a detailed timeline for achieving compliance with the applicable requirements. In the CY 2023 PFS final rule, we finalized a policy at § 414.1400(e)(1)(i)(E) to require third party intermediaries to provide a communication plan for communicating the impact to the parties identified within the corrective action plan (87 FR 70107).

Based on our experience with corrective action plans from third party intermediaries through the years, we have identified a gap in our ability to determine if certain elements of the corrective action plan have been completed in the time and manner specified within the action plan. Therefore, we propose to add at § 414.1400(e)(1)(i)(F) an additional requirement for a third party intermediary under a corrective action plan to communicate the final resolution to CMS once the resolution is complete, and to provide an update, if any, to the monitoring plan provided under § 414.1400(e)(1)(i)(C). We believe this additional step will ensure that third party intermediaries complete the required actions within the corrective action plan.

We invite comments on this proposal.

(d) Public Posting of Deficiencies

In the CY 2017 Quality Payment Program final rule (81 FR 77386 through 77388), we established a remedial action that, in the event that a QCDR or qualified registry had data inaccuracies that affected more than 3 percent but less than 5 percent of the total number of MIPS eligible clinicians, we would have this information identified on the CMS public posting. We modified this requirement in the CY 2019 PFS final rule (83 FR 59909) that the data error rate would be publicly disclosed until the data error rate falls below 3 percent.

We are proposing to modify this requirement. While we previously determined that a single, objective measure (that is, a 3 percent error rate) would support our goals of public

notice, we believe that the precise metric is not a meaningful indicator. Specifically, some errors may be minor in nature yet affect a large number of clinicians for whom the QCDR or qualified registry has reported data. Other errors, however, may be materially significant but may not affect 3 percent of the MIPS eligible clinicians due to the unique nature of the data point at issue.

We believe that there is significant value in informing the public and potential customers which QCDRs and qualified registries are under remedial action or are terminated. Therefore, we propose to add a new provision at § 414.1400(e)(1)(ii)(B) that CMS may, beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary. We note that this public disclosure would be limited to the presence of the corrective action plan and would not include any proprietary information from the QCDR or qualified registry. We also propose to modify § 414.1400(e)(1)(ii) by redesignating it as § 414.1400(e)(1)(ii)(A) and ending this policy after the CY 2025 performance period/2027 MIPS payment year. We are proposing to remove this policy because we believe it would be superseded by the proposal included in § 414.1400(e)(1)(ii)(B).

We invite comments on these proposals.

(e) Considering Past Performance in Approving Third Party Intermediaries

In the CY 2017 Quality Payment Program final rule, we established that third party intermediaries would be placed on probation status if they had not met criteria for qualification following self-nomination (81 FR 77386 through 77389). Under the terms of the probation policy, a corrective action plan could be required to address any deficiencies or prevent them from recurring. In addition, a third party intermediary that was on probation status for 2 years would be disqualified for the subsequent performance period. In the CY 2019 PFS final rule (83 FR 59909), we consolidated the corrective actions that we would take in the event of a deficiency or error on the part of a third party intermediary. This included the elimination of a policy of probation for third party intermediaries and the establishment of a policy of remedial action for third party intermediaries. We did not change the factors made to determine a remedial action or probation.

We have continued to experience issues related to data errors from third party intermediaries and these errors often extend over multiple years. We are concerned that some third party intermediaries fail to address deficiencies with regularity, and are required to perform remedial actions as defined in corrective action plans over the course of many years. This suggests that these organizations are not able to properly adhere to the criteria for qualification for third party intermediaries. While we have established criteria for approval of third party intermediary at § 414.1400(a)(2)(ii)(A) which state that our determination to approve a third party intermediary may take into account whether the entity failed to comply with the requirements for a previous MIPS payment year, we wish to clarify that the consideration of past compliance can also include remedial actions. While we already have the ability to consider whether the entity failed to comply with certain requirements, we do not believe that the existing requirements are explicit enough for third party intermediaries to understand that a history of remedial actions, even if addressed such that the third party intermediary was not terminated could result in CMS not approving future approval.

We invite comment on this proposal.

(f) Terms of Audits

In the CY 2017 Quality Payment Program final rule (81 FR 77389 through 77390), we finalized that third party intermediaries submitting MIPS data must comply with auditing procedures as a condition to participate in MIPS. In this rule, we did not establish the reasons we have for auditing a particular third party intermediary. We note that we perform both random and targeted compliance audits based on a number of reasons and we wish to document those reasons for transparency to the public. Therefore, we propose at § 414.1400(f) that third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. For example, areas of concern could include but are not limited to: high data errors, support call absences, delinquent deliverables, remedial action status, clinician concerns regarding the third party intermediary, a continuing pattern of Quality Payment Program Service Center inquiries or support call questions, and/or CMS concerns regarding the third party intermediary. We also propose to redesignate the existing section § 414.1400(f) (which includes paragraphs (f)(1), (2), and (3)) as paragraph (a)(3)(v) with minor changes in the text for clarity. We note that this section refers to program requirements, which we believe is a more appropriate characterization of these requirements.

We invite comments on these proposals.

(7) Technical Changes

In the course of reviewing the regulation for third party intermediaries, we identified areas in which certain language was used that is not as consistent or clear as it could be. We propose to make the following changes to § 414.1400 to improve clarity as denoted below:

- At paragraph (a)(2), to clarify that an organization may only become a third party intermediary for the purposes of MIPS by meeting the approval criteria by replacing the term ''third party intermediary'' with ''organization''.
- Redesignate paragraph (a)(3) to delineate third party intermediary approval criteria from requirements for third party intermediaries as they participate in the Quality Payment Program. We propose the following redesignations:
- § 414.1400(a)(3) redesignated as § 414.1400(a)(3)(i);
- § 414.1400(a)(2)(i)(C) redesignated as § 414.1400(a)(3)(ii);
- § 414.1400(a)(2)(i)(D) redesignated as § 414.1400(a)(3)(iii);
- § 414.1400(a)(2)(i)(F) redesignated as § 414.1400(a)(3)(iv); and
- § 414.1400 (a)(2)(iii) redesignated as § 414.1400(a)(3)(vi).

These reorganized sections also include minor changes to the text. Please note that we discuss new proposals related to these requirements in section IV.A.4.k.(3) of this proposed rule. There is also a conforming change to reference this section at § 414.1400(e)(1).

- At § 414.1400(e)(3) to remove the word ''total'' from the phrase ''total clinicians'' as this word was included in error.
- At § 414.1400(e)(4) to improve clarity and remove a paragraph.

We invite comments on these proposals.

l. Public Reporting on Compare Tool

Section 10331(a)(1) of the Affordable Care Act provides for the development of a Physician Compare internet website (''Physician Compare'') with information on physicians and other eligible professionals enrolled in Medicare who participate in the

Physician Quality Reporting Initiative (PQRI). Section 1848(q)(9) of the Act, as added by section 101(c) of MACRA, aligned Physician Compare with the newly established Merit-Based Incentive Payment System (MIPS) by requiring the public reporting of MIPS performance information for MIPS eligible professionals through Physician Compare.

For previous discussions of public reporting of physician and clinician performance and information, we refer readers to the CY 2016 Physician Fee Schedule (PFS) final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2022 PFS final rule (86 FR 65550 through 65554), the CY 2023 PFS final rule (87 FR 70109 through 70113) and the Care Compare: Doctors and Clinicians Initiative web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*. We also note that as finalized at § 414.1305 ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, we note the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as the ''Compare tool'' throughout prior rulemaking and this proposed rule (86 FR 39466). (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*.)We also note that as finalized at § 414.1305 ''Physician Compare'' is defined as the Physician Compare internet website of CMS (or a successor website). As discussed in prior rulemaking, we note the current website is the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as the ''Compare tool'' throughout prior rulemaking and this proposed rule (86 FR 39466).

(1) Telehealth Indicator

In the CY 2023 PFS final rule, we finalized the addition of an indicator to the profile pages of clinicians who furnish telehealth services (87 FR 70109 through 70111) to established processes and coding policies to identify such clinicians (*id.*). Among the originally proposed policies, we proposed using Place of Service (POS) code 02 (indicating telehealth) on paid physician and ancillary service (that is, carrier) claims or modifier 95 appended on paid claims (87 FR 46330). During the CY 2023 PFS proposed rule public comment period, we received unanimous support for adding a telehealth indicator. One of the commenters also brought to our attention a POS coding update, and we subsequently finalized a policy of using both POS 02 and POS 10, as well as modifier 95 to identify clinicians that furnish telehealth services.

At the time of the CY 2023 PFS proposed rule, we were not aware of an update in process for POS Code 02 revising the description from ''telehealth'' to ''telehealth provided other than in patient's home'' for locations in which telehealth services were furnished. In connection with this change to POS Code 02, Medicare also adopted the then newly added POS Code 10, ''telehealth provided in patient's home.'' Since many telehealth visits occur in patients' homes it was appropriate and consistent with the intent of our proposal to include POS 10 in addition to POS 02 and claims modifier 95 to identify clinicians providing telehealth services in our final policy.

The POS Code 10 comment, described earlier in this section, received in response to our proposal in the CY 2023 PFS proposed rule, inferred the need to stay current with all types of coding changes that occur throughout the year, outside of the annual PFS rulemaking cycle. Under our current policy, we would already be using the most current CPT codes for each telehealth indicator update; however, we would need to use annual rulemaking to update the POS and claims modifier codes used for telehealth indicator public reporting purposes. Depending on how frequently codes are updated, there could be the unintended consequence of using the annual rulemaking cycle to adopt updated codes that could otherwise be avoided through establishing a coding flexibility policy. If we are limited to the codes specifically finalized via rulemaking, the codes used to inform the telehealth indicator may be incomplete or outdated when we refresh the telehealth indicator on clinician profile pages throughout the year, resulting in users of the Compare tool receiving incorrect information.

Adding coding flexibility for other codes, such as POS and claims modifiers, would both help avoid future regulatory burden and allow for more real-time accuracy of the telehealth information provided on Care Compare. This is particularly important since consumer testing and 1–800–MEDICARE inquiries have shown that patients and caregivers are actively looking for telehealth services, as well as for health equity purposes since telehealth is critical to those who live in rural areas, lack transportation, or have other limitations.

For these reasons, we are proposing to update our policy for identifying clinicians furnishing telehealth services, such that we remain current with CMS coding changes, without proposing and finalizing such coding changes via rulemaking. Specifically, instead of only using POS code 02, 10, or modifier 95 to identify telehealth services furnished for the telehealth indicator, we would use the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth. This flexibility is consistent with how we use the most current CPT codes, some of which are time-limited, to identify clinicians furnishing telehealth services. We are proposing that at the time of such a data refresh we would publish the details of which codes are used for the telehealth indicator through education and outreach, such as via a fact sheet, listserv, and information posted on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*. We are seeking comment on this proposal.

(2) Publicly Reporting Utilization Data on Profile Pages

Section 104(a) of MACRA provides that, beginning with 2015, the Secretary shall make publicly available on an annual basis, in an easily understandable format, information with respect to physicians and, as appropriate, other eligible professionals, on items and services furnished to Medicare beneficiaries. The information made available must be similar to the physician and other supplier utilization data we have historically made available through the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (''PUF'') and shall include information on the number of services furnished by the physician or other eligible professional under Medicare, which may include information on the most frequently furnished services or groupings of services. Section 104(e) of the MACRA requires that we integrate this data into the Compare tool. We finalized a policy to report the most recent available utilization data in downloadable format beginning in late 2017 (80 FR 71130). This information

continues to be available today in the Medicare Provider Data Catalog (PDC) available at *https://data.cms.gov/provider-data/topics/doctors-clinicians*. Separately, we have reported on the Compare tool clinician training information as well as a clinician's primary and secondary specialties.

In the CY 2023 PFS final rule, we established a policy for publicly reporting procedure information on clinician profile pages to provide patients more information in their clinician searches in an understandable format, beginning no earlier than CY 2023 (87 FR 70111 through 70113). Until that time, we had gathered utilization data for procedures from physician/supplier Medicare Part B non-institutional claims on certain services and procedures and published it in the Physician and Other Supplier Data PUF. Although these data are useful to the healthcare industry, healthcare researchers, and other interested parties, this information was presented in a technical manner that was not easily accessible or usable by patients, who do not frequently visit *https://data.cms.gov* or understand medical procedure coding.

We also established that priority procedures selected for utilization data public reporting will meet one or more of the following criteria:

- Have evidence of a positive relationship between volume and quality in the published peer reviewed clinical research;
- Are affiliated with existing MIPS measures indicating importance to CMS;
- Represent care that a patient might shop for a clinician to provide; and/or
- Are an HHS priority.

We finalized that this data would be based on a 12-month lookback period, with data refreshes updated bi-monthly, as technically feasible, and we would not initially prioritize complex, rare procedures. We noted that the utilization data shown on profile pages would only reflect Medicare Fee-for-Service (FFS) claims data and would not include procedures performed for patients who have other types of insurance. To meaningfully categorize procedures, we finalized the policy of using the Restructured Berenson-Eggers Type of Service (BETOS) Codes Classification System to collapse Healthcare Common Procedure Coding System (HCPCS) data into procedural categories, and when no Restructured BETOS categories are available, procedure code sources used in MIPS, such as the procedure categories already defined for MIPS cost or quality measures. Restructured BETOS is a taxonomy that allows for the grouping of procedure codes into clinically meaningful categories and subcategories. Additional Restructured BETOS information is available at *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system*. These category sources, as finalized, allow us to publicly report procedural utilization data in a meaningful way to patients and caregivers rather than showing thousands of rows of individual HCPCS data, as we do for the research community in the PDC. For example, applying categories enables us to list that a clinician performs knee arthroplasties. Using plain language, we would simplify the procedure category name to ''knee replacements'' for understandability instead of listing each of nine unique procedure codes indicating the specifics of exactly which bones and which implants were involved.

Since the publication of the CY 2023 PFS final rule, we conducted additional consumer testing and data analysis to prepare and select certain procedure-related utilization data for publication. Consumer testing showed that publicly reporting utilization data on patient-facing clinician profile pages and using plain language, is helpful for patients and caregivers to make informed healthcare decisions, since it allows them to find clinicians who have performed specific types of procedures. Consumer testing results showed that patients and caregivers understand this language, would not select a health care provider based on this information alone, and find the information helpful but would like the procedure volume to also reflect patients with other insurance if possible. Our data analyses have confirmed the availability of Medicare Advantage (MA) data increasing the representativeness of the procedure (that is, utilization) data, as discussed later in this section.

We are targeting to release procedure data based on FFS claims on clinician profile pages later this year, beginning with 13 priority procedure categories identified for public reporting. Details on the utilization data publicly reported on clinician profile pages will be available on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative* and on the PDC at *https://data.cms.gov/provider-data/dataset/eedd-4c6c*.

(a) Updating the Provider Data Catalog (PDC) Utilization Data Policy

As discussed earlier in this section, we historically have published a PDC file that is a subset of the most commonly performed procedures in the PUF. With the upcoming release of the initial procedural utilization data, we will publish a second utilization file in the PDC that will reflect the procedure category information on clinician profile pages. That is, consistent with what will be publicly reported on profile pages, the second PDC file will aggregate like procedures and include an indication of low volume counts, in accordance with the CMS small cell size policy, in which counts below 11 cannot be publicly reported, to protect patient privacy.

It would be of greater use for the PDC to only have one utilization downloadable file that reflects the same subset of data, in the same format, as what will be publicly reported on clinician profile pages. Doing so aligns the criteria for selecting utilization data in the PDC to reflect the same criteria for selection on clinician profile pages and will assist researchers in analyses of utilization data on clinician profile pages. Moreover, the researcher and clinician communities, who are the primary users of the PDC, would appreciate having the single downloadable dataset that reflects the same procedure utilization data that would appear on clinician profile pages. It would also be more efficient to focus resources on maintaining one file reflective of clinician profile page utilization data rather than both produce that file and duplicate some of the PUF information on the PDC. The full CMS PUF of FFS data is still available on *https://data.cms.gov* for researchers and clinicians who are interested in the full set of Medicare procedure information at the individual procedure code level. To direct researchers to the PUF of Medicare FFS information, we currently communicate where to locate the original PUF and the details of the updated PDC file through education and outreach, such as via a fact sheet, listserv, and information posted on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-initiative*.

Therefore, we propose revising the policy to publicly report a subset of the Medicare PUF on the PDC to instead provide a single downloadable dataset including the procedure utilization data that would appear on clinician profile pages. If this proposal is finalized, we

would remove the PUF subset file from the PDC and only keep the utilization data file that reflects the information on clinician profile pages in the PDC.

We seek comment on all aspects of this proposal, including any concerns about technical feasibility; our proposed approach to aligning the criteria for selecting utilization data in the PDC to reflect the same criteria for selection on clinician profile pages; ways in which we inform researchers on the location of the full CMS PUF for continued use; and any other considerations. The proposals discussed later in sections IV.A.4.l.(2)(b) and (2)(c) would also be reflected in the new downloadable utilization data file in the PDC if the other proposals are finalized as proposed.

(b) Procedure Grouping Policy for Publicly Reporting Utilization Data

As mentioned earlier in this section, in the CY 2023 PFS final rule, we finalized using Restructured BETOS and procedure code sources used in MIPS when no Restructured BETOS categories are available, such as the procedure categories already defined for MIPS measures to meaningfully categorize procedures for public reporting (87 FR 70111). However, since finalizing this policy, we identified some commonly sought procedures, such as hysterectomy, that do not have a procedure category specified in the Restructured BETOS categorization system or a relevant code set in any MIPS quality or cost measures. We anticipate this issue could occur for additional procedures as we continue to identify additional priority procedures for public reporting.

We received a few comments on the CY 2023 PFS proposed rule that stated that some of the Restructured BETOS categories may be too broad and acknowledged that there is no other existing standard, systematic way to group procedures by HCPCS codes (87 FR 70111 and 70112). However, we did not receive any suggestions for alternative sources for the purpose of grouping procedures during the CY 2023 PFS proposed rule public comment period.

We now propose to define meaningful categories using subject matter expert (for example clinician) input in instances where a procedure category is unavailable under the Restructured BETOS or MIPS measures, if a code category exists but is not suitable for public reporting, or in instances where a procedure category does not exist, to create new, clinically meaningful, and well-understood procedure categories as needed. Added flexibility in grouping HCPCS codes to create procedure categories meaningful to patients and caregivers would allow users of the Compare tool to better assess a clinician's volume and scope of experience with a particular procedure and inform healthcare decision making.

To implement this, we are proposing to modify the existing policy such that, in addition to the two previously finalized sources (Restructured BETOS categorization system and code sources used in MIPS), we may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists. If we develop new procedure categories for publicly reporting utilization data on clinician profile pages, we propose to engage subject matter experts and interested parties through periodic requests for feedback using methods outside of rulemaking, such as listserv emails, listening sessions, and focus groups to solicit feedback on bespoke procedure categories planned for future releases of utilization data, as appropriate and technically feasible.

We are seeking comment on all aspects of our proposal to modify existing procedural categorization policy to use alternate sources to create clinically meaningful and appropriate procedural categories and our proposed approach to engaging with subject matter experts in developing procedure categories, as appropriate and technically feasible.

(c) Incorporating Medicare Advantage (MA) Data Into Public Reporting

Between the time of the CY 2023 PFS proposed and final rules, our Medicare FFS claims data analyses showed that for the initial 13 priority procedures identified, approximately 50 percent of clinician-procedure combinations fall into the low volume category, which meant that, based on Medicare physician and ancillary service (carrier) claims in the past 12 months, we could only publish an indicator that a clinician has experience with the procedure rather than specific counts. Under the small cell size policy, we prohibit the use of specific procedure or patient counts in cases where the count is below ten. The high number of clinicians with a low volume indicator is partly due to not including data for patients with other coverage, such as MA plans or other payers, for whom a given clinician has also performed such procedures. As such, we are currently limited in our ability to contextualize low volume clinician experience with procedures in a way that is useful and easily understandable for patients and caregivers who may be looking for a clinician with experience performing a specific procedure.

As we identify more priority procedures for public reporting, more procedures may be subject to the small cell size policy using Medicare FFS data alone, which would prevent us from publicly reporting health care provider experience with such procedures for patients and caregivers to use in their healthcare decisions. Based on public comments and consumer testing, including other payer data would help prevent this issue. Specifically, we received several comments on the CY 2023 PFS proposed rule from the clinician community who had expressed concern about the understandability of the data and that limiting procedure data counts to Medicare FFS claims only does not reflect the full scope of clinician practice (87 FR 70112). Consumer testing findings have also shown that patients and caregivers would like procedure information to reflect all procedures performed, since it better represents clinicians' experience.

While we agreed with comments received on the CY 2023 PFS proposed rule, we were unable to finalize the possibility of using other payer data as appropriate and technically feasible at that time. However, we have subsequently determined through analysis of MA encounter data submitted to CMS that it would be technically feasible to integrate MA encounter data into procedure category counts and that adding such data adds to the representation of some clinicians' scope of care. For example, adding MA encounter data to the initial set of publicly reported procedure categories would reduce the low volume clinician-procedure counts by approximately 12 percent. An additional 10,689 unique clinicians would have information on their profile pages, since they do not have this information based on FFS data alone. These unique clinicians account for furnishing 9 percent (10,869/114,243) of the combined FFS and MA patient populations from July 1, 2021 to June 30, 2022.

Therefore, we are proposing to publicly report aggregated counts of procedures performed by providers based on MA encounter data in addition to Medicare FFS utilization data, given that we have determined it is appropriate and technically feasible. Section 104(a) and (b) of MACRA provides for the public reporting of items and services furnished to Medicare beneficiaries under title XVIII of the Act, including, at a minimum, information on the most frequent

services or groupings of services furnished by physicians or other eligible professionals under part B of title XVIII of the Act. This provision authorizes the publication of information on the items and services furnished to ''Medicare beneficiaries under Medicare by physicians and certain other professionals.'' Notably, the statute authorizes the disclosure of information on all items and services furnished to Medicare beneficiaries under the Medicare Act; that is, the statute does not limit the disclosure to a particular subset of Medicare services. Indeed, section 104(c)(1) of MACRA provides that the information made available must include ''at a minimum'' certain information on Part B services. This does not limit the disclosure authorized by section 104(a) of MACRA to information on Part B items and services; instead, it specifies the minimum information that CMS must disclose, leaving additional disclosures under section 104(a) of MACRA to CMS' discretion. MA plans cover Part A and Part B benefits (excluding hospice services, acquisition costs for kidneys used for transplants, and, for a limited period, certain services under new National Coverage Determinations and changes in legislation) for Medicare beneficiaries that elect to enroll in an MA plan; this coverage is also under Title XVIII of the Act. Section 104(a) of MACRA thus authorizes the disclosure of certain information about items and services provided as benefits under an MA plan and furnished by a physician or other eligible professional.

Separately, section 10331(b)(4) of the Affordable Care Act provides for the Secretary to, in developing and implementing his plan to make information as determined appropriate by the Secretary available on Physician Compare, include data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent practicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance. Thus, the inclusion of MA encounter data is consistent with the relevant statutory provisions regarding the disclosures on the Care Compare website.

Per section 1853(a)(3)(B) of the Act, CMS has required MA organizations to submit the data necessary to characterize the context and purposes of each item and service provided to a Medicare beneficiary enrolled in an MA plan to use for risk adjusting payments by CMS to MA plans. Per the MA regulation at § 422.310(f)(1)(vii), CMS may use this risk adjustment data, which includes MA encounter data, for activities to support administration of the Medicare program and for purposes authorized by other applicable law. The MA regulation at § 422.310(f)(2) allows CMS to release encounter data for any of the purposes specified in § 422.310(f)(1) in accordance with applicable Federal laws and CMS data sharing procedures, subject to protections of beneficiary confidentiality and commercially sensitive data. Finally, § 422.310(f)(3) imposes restrictions on when the data is available for release. We propose to rely on § 422.310(f), as well as section 104 of the MACRA and section 10331 of the Affordable Care Act, for using and releasing the MA encounter data as part of the Care Compare website. To accomplish this, we are also proposing to amend § 422.310(f)(3) to permit the release of the MA encounter data on the timeframe(s) used for disclosure and release of the data on the Care Compare website. This proposal would ensure that there is no confusion about our ability to use and release the MA encounter data for the Care Compare website and downloadable files and permit release of MA when necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

Using and analyzing MA encounter data as part of the aggregated information disclosed through the Care Compare website will more completely fulfill the public reporting required by section 104 of the MACRA and section 10331 of the ACA and using the MA encounter data in implementing these statutory provision supports administration of the Medicare program. In addition, it is also consistent with administering the Medicare program overall to provide appropriate and helpful information to beneficiaries in selecting a provider. Thus, the use and disclosure of the MA encounter data here are within the scope of § 422.310(f)(1)(vii).

The aggregated utilization data we propose to include in the Compare tool meets the additional requirements to protect beneficiary and commercially sensitive information at § 422.310(f)(2) because only identifying information about healthcare providers and types of procedures performed within a specific time period would be disclosed on the website and available for release in the PDC downloadable files. The disclosure and release of these portions of the MA encounter data are consistent with CMS data sharing procedures, which are applied to the Medicare FFS data already displayed and available for download on the Care Compare website. However, when releasing the MA encounter data under § 422.310(f)(2), the timing limitations at § 422.310(f)(3) prohibit releasing encounter data before the applicable payment year's reconciliation has been completed except for in specified circumstances. Neither of the exceptions applies here. Because we propose to use information from the MA encounter data, in combination with FFS claims data, over a 12-month rolling period, but risk adjustment reconciliation occurs no sooner than 13 months after the end of the year that services were provided, the timing of the proposed release of the MA encounter data is not within the scope of the timing requirements in § 422.310(f)(3).

MA organizations submit encounter data continuously, but do not have the same timeliness requirements for submission that FFS providers have for submitting claims. In the August 22, 2014 final rule entitled, ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program'' (79 FR 49854), CMS adopted § 422.310(f)(3) to address concerns that the need to update or correct MA encounter data prior to the final submission deadline could mean that the MA encounter data was not sufficiently complete or fully reliable for public release. However, since that time, which was during the first few years of submission of MA encounter data to CMS, submissions of MA encounter data have improved. In particular, the provider identifying information and procedure codes required for the Compare tool are well reported. Because the Compare tool is reporting aggregated counts of procedures, and not at the beneficiary level, releasing this data before final reconciliation is appropriate to support the administration of the Medicare program. Furthermore, including utilization and limited provider-identifying data from MA encounters prior to the data being reconciled by the MA organization would substantially improve the Compare tool and, thereby, the administration of the Medicare program overall by providing patients and

caregivers with more useful and easily understandable information about procedures performed by providers in their search for a clinician. We therefore propose to amend § 422.310(f)(3) to include an additional exception at (f)(3)(iv) that permits CMS to release aggregated risk adjustment data before the reconciliation for the applicable payment year has been completed if CMS determines that releasing aggregated data is necessary and appropriate for the purposes specified in § 422.310(f)(1)(vii).

Based on our analyses, the inclusion of data about utilization in the MA program would reduce the low volume procedure counts subject to the small cell size policy, in which precise counts less than ten procedures or patients cannot be publicly reported. This would allow us to more accurately report the types of services that Medicare clinicians provide. Based on the public comments in our prior rulemakings about the Care Compare website and consumer feedback, aggregating utilization data from the Medicare FFS and MA program would also enhance patient use of the information. Although the initial release of publicly reported utilization data on the Compare tool is limited to clinicians' Medicare FFS claims, publicly reporting utilization data that includes Medicare FFS and MA would also be more consistent with MIPS quality information submitted via health IT vendors or registries that include other payer data. Lastly, adding MA data to the counts in the existing Medicare FFS utilization data file will mitigate interested party concerns by ensuring the data is more reflective of the physician's/clinician's scope of practice.

We seek comment on all aspects this proposal.

(3) Request for Information: Publicly Reporting Cost Measures

Section 1848(q)(9)(A)(i) of the Act requires us to publicly report MIPS eligible clinicians' final scores and performance category scores and authorizes, but does not require, us to publicly report MIPS eligible clinicians' performance with respect to each measure or activity. In the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), we finalized our policies for publicly reporting MIPS eligible clinicians' and groups' final scores, performance category scores, and measure-level scores in an easily understandable format. Currently, we publicly report certain MIPS performance information that meet public reporting standards on clinician, group, and Accountable Care Organization (ACO) profile pages of the Compare tool (available at *https://www.medicare.gov/care-compare/*) so Medicare patients and caregivers can use it when making healthcare decisions. In addition to publicly reporting final scores and performance category scores in the PDC, we established a policy to publicly report performance on measures, activities, and attestations, from the MIPS quality, cost, Promoting Interoperability (previously called Advancing Care Information), and improvement activities performance categories that meet established public reporting standards (81 FR 77395). We codified these public reporting standards in our regulations at § 414.1395(b), requiring that performance data be statistically valid, reliable, accurate, and comparable across collection types, to be included in the PDC, available at *https://data.cms.gov/provider-data/topics/doctors-clinicians.* The data must also resonate with patients and caregivers as determined by user testing to be included on the Compare tool profile pages.

As of the time of this proposed rule, data from the CY 2021 performance period/2023 MIPS payment year regarding MIPS eligible clinicians' performance in the quality, improvement activities, and Promoting Interoperability performance categories that meet public reporting standards are publicly available on Compare tool profile pages and in the PDC. However, we have not publicly reported any cost measure information from the cost performance category since the inception of MIPS for two primary reasons.

First, in the CY 2019 PFS final rule (83 FR 59910 through 59912), we established a policy to delay publicly reporting any new quality and cost measures for the first two years they are in MIPS to allow MIPS eligible clinicians and groups to gain experience with the new measures. We codified this policy in our regulation at § 414.1395(c). After this period, we would reevaluate the measures to determine when and if they are suitable for public reporting (83 FR 59910 through 59912). Second, we have not had cost measures available for public reporting because of the COVID–19 Public Health Emergency (PHE), during which we reweighted the cost performance category to zero percent for MIPS eligible clinicians' final scores in the CY 2019 performance period/2021 MIPS payment year, as discussed at *https://qpp.cms.gov/resources/covid19?py=2019,* the CY 2020 performance period/2022 MIPS payment year, as discussed at *https://qpp.cms.gov/resources/covid19?py=2020,* and the CY 2021 performance period/2023 MIPS payment year, as discussed at *https://qpp.cms.gov/resources/covid19?py=2021.* That is, for several years, we provided cost measure scores to clinicians for informational purposes only and did not publicly report MIPS eligible clinicians' performance in the cost measure category.

However, given the number of cost measures we have adopted in MIPS for at least two years and the PHE ending, we are evaluating ways to publicly report performance on cost measures on clinician and group profile pages beginning with data from the 2024 performance period/2026 MIPS payment year being publicly reported in 2026. Public reporting of these data would assist patients and caregivers in making healthcare decisions. In section IV.A.4.f.(2) of this proposed rule, we are proposing, beginning with the CY 2024 performance period/2026 MIPS payment year, adoption of five new episode-based cost measures and removal of one episode-based cost measure. If our proposal is finalized, there would be a total of 25 cost measures—23 Episode-Based Cost Measures (EBCMs), Medicare Spending Per Beneficiary (MSPB), and Total Per Capita Cost (TPCC)—available for public reporting in CY 2026, provided they meet public reporting standards as set forth in our regulation at § 414.1395. In the CY 2019 PFS final rule (83 FR 59910 through 59912), we finalized a policy to delay publicly reporting any new quality and cost measures for the first 2 years they are in MIPS at § 414.1395(c). There are currently 25 cost measures available for public reporting at the time of this Request for Information, and the 5 cost measures proposed for inclusion in section IV.A.4.f.(2) of this rule would not be eligible for public reporting until the CY 2026 performance period/2028 MIPS payment year. Additionally, by publicly reporting cost measures, we would further our goals of transparency, encouraging MIPS eligible clinicians to prioritize cost efficiency, and enabling patients and caregivers to make informed decisions about clinicians who consider costs as part of their care.

Research suggests that patients and caregivers are interested in comparative cost information.[320] An Agency for

[320] Greene, J., & Sacks, R.M. (2018). Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices. Health services research, 53 Suppl 1(Suppl 1), 2662–2681. *https://doi.org/10.1111/1475-6773.12839.*

Healthcare Research and Quality (AHRQ) environmental scan and systematic review of all payer claims databases (APCDs) in 2017 found there is a need for standardized and transparent cost measures reporting, as well as user-friendly interfaces that help patients and caregivers make informed healthcare decisions.[321] Several sources highlight the importance of presenting cost information in the context of quality metrics to improve healthcare consumers' ability to interpret cost data.[322] [323] Although there is limited research in this area, there is evidence that consumers can make high-value choices using cost in combination with other performance data.[324]

During a recent consumer testing session with patients, the majority of whom were Medicare beneficiaries and included two retired clinicians, several participants noted that they find cost information valuable and would use it in conjunction with other information when making healthcare decisions. This early finding suggests that this type of information is valued by healthcare consumers; additional consumer testing with patients and caregivers and input from clinical subject matter experts would be beneficial for gathering feedback from the population who use the website and ensure that publicly reported MIPS cost measures are interpreted correctly and useful to website users. Further consumer testing with patients and caregivers would also help determine which aspects of cost performance information resonate most with them, as well as how to best display and plain language cost measure information on clinician and group profile pages.

We intend to propose in future rulemaking to publicly report MIPS cost measures beginning with data from the CY 2024 performance period/2026 MIPS payment year in CY 2026 on Compare tool clinician and group profile pages and in the PDC in 2026. In this Request for Information (RFI), we are seeking comment on a number of aspects of how to best establish publicly reporting cost measures, as discussed below.

- Potential approaches to reporting MIPS cost measures, including whether it is more meaningful to only report aggregated episodes or include component-level cost information for the EBCMs. Cost measure components are specified in the measure construction for each episode type based on input from clinical expert engagement activities during the development process and can include services related to either clinical treatments or adverse events (for example, clinically related diagnostic care, the need to receive post-acute care following the initial procedure or hospitalization, and the need to visit an emergency room or be readmitted for additional inpatient care following the initial procedure or hospitalization). With this context, patients would have additional information enabling them to make informed healthcare decisions.

To provide actionable cost measure data, we will test the consumer perceptions of the components of cost measures in addition to the overall cost measure scores to determine whether they resonate with users. We expect that component costs will provide context for patients and caregivers to understand the extent to which costs are driven by what may be perceived as high-quality care (for example, post-discharge follow-up visits) or low-quality care (for example, procedure re-do). For example, when comparing clinicians, consumers could assess frequency or severity (for example, as measured by above average costs associated with clinically related complications).

- Benchmarking and possible comparators as well as how to best present this information to provide frames of reference for the cost performance information. Cost measures present a unique challenge to public reporting as their interpretation is not intuitive to consumers. While higher than expected costs may be driven by adverse outcomes, overall cost is comprised of care components that consumers could perceive as higher quality (for example, follow-up visits) as well as lower quality (for example, clinically related emergency department visits and re-hospitalizations). As a result, overall costs alone do not provide sufficient context about the drivers of those costs and may cause consumers more confusion in making a choice about where to seek care. Publishing overall costs could also be misleading, as previous consumer testing showed that some patients and caregivers interpret higher costs as a reflection of higher quality, when in fact testing during cost measure development has consistently demonstrated that clinicians with higher shares of costly adverse events, such as hospital readmission, tend to have worse scores.

One mechanism of contextualizing cost measure performance is through displaying cost measures alongside clinically relevant quality measures, resulting in a reflection of value. However, there are two main reasons the current structure of MIPS does not consistently support this preferred display. First, under the self-selection policy for quality measures, MIPS eligible clinicians may select measures on which they expect to score best, rather than those that are most clinically relevant to their practice. This can result in a clinician profile with quality measures that are clinically unrelated to the clinician's core practice activities and, therefore, the clinician's cost measures. Second, MIPS eligible clinicians have a choice between reporting their performance on quality measures as individuals or as part of a group. Group-reported quality measure performance cannot be disaggregated to the clinician level. Because we calculate cost measures independently for all eligible clinicians and groups using Medicare claims, performance information is available at both levels. When reporting cost measure performance at the clinician level (because patients and caregivers using the Compare tool prefer measure performance at the most granular level available), we could have cost measures on a MIPS eligible clinician's profile page with no accompanying quality measures. Given these realities inherent to MIPS, there may not always be relevant quality measure information available to display alongside cost for a value concept. MIPS Value Pathways (MVPs) may mitigate some of these issues, since clinicians would have a smaller set of quality measures, some of which could be more related to their specialty, for selection, but clinician versus group level performance reporting discrepancies would persist.

Therefore, we have considered several approaches to presenting cost measure performance information without assuming related quality measures would be available for adjacent display, including reporting the ratio of cost to the national average cost and the dollar cost per episode. These approaches may result in challenges to interpreting meaningful differences in costs. The

[321] Agency for Healthcare Research and Quality, All-Payer Claims Databases Measurement of Care: Systematic Review and Environmental Scan of Current Practices and Evidence (2017) *https://www.ahrq.gov/data/apcd/envscan/findings.html.*

[322] Greene, J., & Sacks, R.M. (2018). Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices. Health services research, 53 (Suppl 1), 2662–2681. *https://doi.org/10.1111/1475-6773.12839.*

[323] Commonwealth Fund, Hospital Price Transparency: Making It Useful for Patients, (2019), available at *https://www.commonwealthfund.org/blog/2019/hospital-price-transparency-making-it-useful-patients.*

[324] Greene, J., & Sacks, R.M. (2018). Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices. Health services research, 53 (Suppl 1), 2662–2681. *https://doi.org/10.1111/1475-6773.12839.*

Achievable Benchmark of Care (ABC™) methodology we currently use to star rate performance on publicly reported MIPS quality and Promoting Interoperability measures would not be appropriate for cost measures, because this method is used for measures in which a single direction of performance (for example, higher) is universally desirable, which, as discussed previously, is not always the case with cost performance. We have also considered an approach to display the MIPS eligible clinician's or group's relative position in the distribution of the cost measure performance compared to the national average we calculate from MIPS cost measures using three levels. Doing so, we could determine whether each clinician or group performance on each scored cost measure is ''greater than,'' ''less than,'' or ''no different'' compared to the national average cost.

We are inviting comment on this possible approach to publicly reporting individual MIPS eligible clinician's or group's performance on individual EBCMs, MSPB, and TPCC compared to the average performance of all MIPS eligible clinicians nationally. We are also seeking comment on considerations for these comparators or benchmarks discussed above, particularly whether they would be useful to present or if there are any alternatives we have not yet considered.

To summarize the aspects discussed above in which we request additional information, we are seeking comment on the following topics related to public reporting of MIPS cost measures on the Compare tool:

- How can we present MIPS cost measures information in a way that reflects meaningful outcomes to patients and their caregivers and the value of care, rather than cost alone?
- What are the considerations for publicly reporting the total episodic cost, component-level costs, or both? Do the component costs provide adequate context for patients and their caregivers to make informed healthcare decision? What other specific information about MIPS cost measures, including the context of quality measures and MVPs, should we consider including on the Compare tool?
- What are the considerations for publicly reporting the national average cost, ratio of cost to the national average cost, and/or the dollar cost per episode as possible benchmarks for comparison discussed above in this section? What other benchmarks or comparator approaches should we consider?
- Are there any considerations for evaluating cost measures for public reporting beginning with cost measure data from CY 2024 performance period/2026 MIPS payment year in the CY 2026?
- What other factors, such as those related to health equity, should be taken into consideration?
- We request comment on additional information that we may not have considered or discussed above about publicly reporting MIPS cost measures, as well as any unintended impacts and/or positive outcomes that could result from making this information publicly available on the Compare tool.

n. Overview of QP Determinations and the APM Incentive

(1) Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables us to advance accountability and encourage improvements in care. The Secretary has also adopted the closely related goal of having all people with Traditional Medicare in an accountable care relationship with their health care provider by 2030, where their needs are holistically assessed and their care is coordinated within a broader total cost of care system. Our vision for increased participation among clinicians in Advanced APMs is driven by a belief that integrating individuals' clinical needs across a spectrum of providers and settings will improve patient care and population health.

As we continue to improve the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad clinician participation in Advanced APMs. For example, in this section, we are proposing to calculate QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM. As discussed further in the proposal, we believe that this change will provide a more accurate measure of the actual engagement of individual clinicians participating in Advanced APMs. This accuracy is important for administration of the Quality Payment Program incentives and also could help us better identify and understand the motivating factors and indicators of clinician readiness for greater adoption of Advanced APMs.

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy at § 414.1425(b) for Qualifying APM Participant (QP) determinations. For the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any one of such dates is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for the eligible clinicians in an APM Entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations at the APM Entity group level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List for more than one APM Entity, but do not to achieve QP status based on any APM Entity-level determinations, we make QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM, we make QP determinations at the individual level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

(2) Individual QP Determination

Under the current policy at § 414.1425(b), most eligible clinicians participating in Advanced APMs receive their QP determinations at the APM Entity level. In the CY 2017 Quality Payment Program proposed rule (81 FR 28319), we contemplated that ''as with any group assessment, there will be some situations in which individual Threshold Scores would differ from group Threshold Scores if assessed separately. This could lead to some eligible clinicians becoming QPs when they would not have met the QP Threshold individually (a 'free-rider' scenario) or, conversely, some eligible clinicians not becoming QPs within an Advanced APM Entity when they might have qualified individually (a dilution scenario).'' At that time, we believed that the benefits of performing QP determinations for the APM Entity as a group outweighed these potential

scenarios. However, as we previously indicated in a Request for Information in the CY 2023 PFS proposed rule (87 FR 46337 through 46339), we have come to believe that the effects of these types of scenarios, including effects that we had not intended or foreseen in the 2017 rule, have come to outweigh the benefits of performing QP determinations at the APM Entity level.

First, it has been brought to our attention that our policy to conduct most QP determinations at the APM Entity level may have inadvertently discouraged some APM Entities from including certain types of eligible clinicians, particularly in multi-specialty APM entities such as ACOs, leading those clinicians to be excluded from participation in Advanced APMs. Because the APM Entity Threshold Scores (using the payment amount and patient count methods) that are used to make APM Entity-level QP determinations are based on an aggregate calculation across all eligible clinicians participating in the APM Entity group, eligible clinicians in the APM Entity group who furnish proportionally fewer services that lead to attribution of patients or payment amounts to the APM Entity are likely to lower the APM Entity's Threshold Score. Many Advanced APMs attribute patients to APM Entity groups based in part on the provision of primary care services, but not all eligible clinicians typically furnish primary care services. For example, primary care physicians may furnish proportionally more evaluation and management (E/M) (office visit) services, which, as we explain more in the next section, are frequently the basis for attribution of patients and payment amounts to the numerator of the APM Entity's Threshold Score, whereas specialist physicians may furnish proportionally more diagnostic tests and surgical procedures, which are not usually part of the attribution basis to the APM Entity.

We have received reports from Advanced APM participants and specialty societies that some APM Entities have taken steps to exclude from their APM Entity groups (and consequently from their Participation Lists) eligible clinicians who furnish proportionally fewer services that lead to the attribution of patients or payment amounts for purposes of calculating Threshold Scores for APM Entity-level QP determinations. For reasons stated above, this action typically would lead to the exclusion of certain specialists from the APM Entity. There are important reasons that it is not beneficial for an APM Entity to exclude specialists and other eligible clinicians who furnish relatively fewer services that lead to attribution. In both the Medicare Shared Savings Program and in models tested by the Innovation Center that the meet the criteria to be Advanced APMs, CMS seeks to promote patient-centered care that is integrated across the continuum of care. The inclusion of specialists in APM Entities is essential for achieving this goal. For example, a comprehensive network that includes a range of specialists is central to the success of an ACO in the Medicare Shared Savings Program for its intended purpose in patient-centered care that coordinates items and services for Medicare FFS beneficiaries, a key aim of value-based care and practice transformation.[325] The methodology used in beneficiary assignment for the Shared Savings Program is deliberately constructed such that assignment is largely based on primary care, rather than specialty care, which results in specialists contributing proportionately less in terms of payment amounts and patient counts to the numerator of the ACO's Threshold Score calculation used for APM Entity-level QP determinations. Similarly, it was not our intent to create a policy whereby eligible clinicians who are seeing most or all of their Medicare patients through an Advanced APM may remain unable to achieve QP status because the APM Entity with which they participate in the Advanced APM includes eligible clinicians who furnish very few services through the Advanced APM. It has always been one of the goals of the APM track of the Quality Payment Program for the availability of QP status to incentivize eligible clinicians to join Advanced APMs. But under our current policy to make most QP determinations at the APM Entity level, there is the potential that eligible clinicians who are fully engaged in an Advanced APM may still be unable to earn QP status. We carefully considered our policy to make most QP determinations at the APM Entity level, and believed it was the best approach at the time. However, we did not intend for the policy to create potentially conflicting incentives for APM Entities between the goal for their eligible clinicians to achieve QP status under the Quality Payment Program, and their full participation in an Advanced APM with a group of eligible clinicians that can deliver a full spectrum of care.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28319), we stated that ''the statute consistently refers to an eligible clinician throughout section 1833(z) of the Act and clearly identifies that the QP determinations are to be made for an eligible clinician,'' then noted that ''in section 1833(z)(3)(B) of the Act, the definition of an eligible clinician includes a group of such professionals.'' While the statutory scheme provides for the flexibility to establish policies that apply for groups of eligible clinicians, it does not require that approach. When we proposed the policy to calculate Threshold Scores at the APM Entity level, we based this policy in part on ''a premise that positive change occurs when entire organizations commit to participating in an Advanced APM and focusing on its cost and quality goals as a whole.'' While we continue to believe in this premise, we also recognize that, if APM Entities are removing or otherwise not including eligible clinicians who may technically contribute less to the APM Entity-level Threshold Score, such actions may impede other worthy goals of the Advanced APM (such as increased care coordination directly among providers caring for a patient), in which case that larger positive change we were seeking to foster is not being achieved.

Conversely, we are concerned that, under our current policy to make most QP determinations at the APM Entity level, in situations where an APM Entity does attain QP status, some eligible clinicians who furnish relatively fewer of their services through that APM Entity may receive a disproportionate financial benefit because their QP status was achieved as a result of the care furnished by other eligible clinicians in the APM Entity while their APM Incentive Payment is calculated based on all of the covered professional services that the individual eligible clinician furnishes during the base year, including services that were not furnished through an Advanced APM. Our policy to make most QP determinations at the APM Entity level allows these windfall financial rewards because we calculate the Threshold Scores using the aggregate of payment amounts or patient counts for attributed patients based on Medicare Part B covered professional services furnished by all the eligible clinicians in the APM Entity, whether an individual eligible clinician furnished a few or many such services. Once an eligible clinician receives QP status for a year, the APM Incentive Payment is calculated based on paid claims for the individual QP's covered professional services across all their TINs in the base year. This can allow an eligible clinician with minimal Advanced APM participation to receive

[325] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about.*

a disproportionately large APM Incentive Payment, which we do not believe aligns with the intent of the Quality Payment Program.

As a result, we have reconsidered our current policy to make most QP determinations at the APM Entity level. Instead, we propose to amend § 414.1425(b) so that, beginning with the QP Performance Period for CY 2024, we would make all QP determinations at the individual level. We note that under §§ 414.1425(b)(2) and 414.1425(c)(4) we currently calculate Threshold Scores at the individual level when the Advanced APM includes eligible clinicians only on an Affiliated Practitioner List, and further, under § 414.1425(c)(4) we also calculate QP determinations individually when the eligible clinician participates in multiple Advanced APMs and does not achieve QP status at the APM Entity level. The proposal would not change our policy for these determinations, but would change the way we make QP determinations for all other eligible clinicians. Under the proposal, we would calculate Threshold Scores for QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM. We would calculate a Threshold Score for each NPI based on all covered professional services furnished across all Tax Identification Numbers (TINs) to which the eligible clinician has reassigned their billing rights. This individual Threshold Score would provide a more specific measurement of each eligible clinician's participation in an Advanced APM. This proposed methodology would ensure that those eligible clinicians who individually meet a QP threshold would receive QP status and its commensurate financial and other benefits. At the same time, it would remove the incentive for APM Entities to exclude certain types of eligible clinicians from their Participation Lists, because the success or failure of the APM Entity's eligible clinicians to reach QP status no longer would be collective. Because each eligible clinician on the APM Entity's Participation List would be evaluated individually at the NPI level, eligible clinicians with lower proportions of payments and payments through the Advanced APM Entity would not affect the QP status of other eligible clinicians on the APM Entity's Participation List.

(3) Payment Amount and Patient Count Methods

In the CY 2017 Quality Payment Program final rule (81 FR 77450 through 77457) we finalized the payment amount method and patient count method for calculation of Threshold Scores used for QP determinations under the Medicare option, and codified these methods at § 414.1435(a) and (b), respectively. The payment amount method is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''Attributed beneficiaries'' to ''Attribution-eligible beneficiaries, as defined at § 415.1305.[326]

Attributed beneficiaries are those who are attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of Attributed beneficiaries at the time of a QP determination. Attribution-eligible beneficiaries generally are those who, during the QP Performance Period, meet six criteria specified in the definition of that term at § 414.1305 and described in section IV.A.4.m.(3) of this proposed rule.

When making QP determinations at the APM Entity or individual eligible clinician level, we begin by calculating Threshold Scores using the payment amount and patient count methods. These Threshold Scores are percentages based on the ratio of the payment amounts or patient counts for Attributed beneficiaries to the payment amounts or patient counts for Attribution-eligible beneficiaries during the QP performance period. If the Threshold Score (using either the payment amount or patient count method) for the eligible clinician or APM Entity, as applicable, meets or exceeds the relevant QP threshold described at § 414.1430(a), the relevant eligible clinicians (either the individual eligible clinician or all those on the APM Entity's Participation List) attain QP status for such year.

FIGURE 3: QP Determination Calculation

$$\frac{\text{Attributed beneficiaries}}{\text{Attribution-eligible benefices}}$$

The regulation at § 414.1435(b)(3) provides that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4), that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups. In the CY 2021 PFS final rule (85 FR 84951 through 84952), we amended § 414.1435(c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the Attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list. This means that beneficiaries who have been attributed to one APM Entity and are thus barred under the terms of an Advanced APM from attribution to another APM Entity are removed from the denominator of the payment amount method and patient count method in QP Threshold Score calculations for the APM Entity to which they cannot be attributed (in other words, we do not penalize an APM Entity in the QP Threshold Score calculation by including a beneficiary in its

[326] For technical information on the QP calculation methodology, see the ''QP Methodology Fact Sheet'' that we publish annually, which can be found as part of the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip*.

denominator when the terms of an Advanced APM do not permit such beneficiary to be attributed to such APM Entity).

(a) Attributed Beneficiary

An Attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. There may be beneficiaries on the most recent available list who do not meet the criteria to be Attribution-eligible beneficiaries because the QP performance period does not coincide with the Advanced APM's performance period or attribution period, or for other reasons. There may be cases where a beneficiary's status changes, for example by enrolling in a Medicare Advantage Plan. We exclude these beneficiaries from our Threshold Score calculations because they do not meet criteria to be Attribution-eligible beneficiaries. Although APMs may have reconciliation processes in place to address changes in beneficiary status at various intervals, those processes do not necessarily coincide with the timeframe of QP determinations. Therefore, when calculating Threshold Scores for QP determinations, we exclude from the list of Attributed beneficiaries any beneficiaries who do not meet the criteria to be Attribution-eligible beneficiaries at that point in time.

(b) Attribution-Eligible Beneficiary

An Attribution-eligible beneficiary is a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

Our stated intent when we finalized the definition of Attribution-eligible beneficiary (81 FR 77451 through 77452) was to have a definition that would, for the purposes of QP determinations, allow us to be consistent across Advanced APMs in how we consider the population of beneficiaries served by an APM Entity. The criteria we used to define Attribution-eligible beneficiary were aligned with the attribution methodologies and rules for our contemporaneous Advanced APMs. The first five criteria are conditions that are required for a beneficiary to be attributed to any Advanced APM. The sixth criterion identifies beneficiaries who have received certain services from an eligible clinician who is associated with an APM Entity for any period during the QP Performance Period. For Most Advanced APMs, we chose to refer to E/M services because many Advanced APMs use E/M services to attribute beneficiaries to their participant APM Entities. Over time we have updated the list of services that are considered to be E/M services for purposes of identifying Attribution-eligible beneficiaries and have published this list as part of the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip.*

We also included an exception in this sixth criterion to allow an alternative approach for Advanced APMs that do not base attribution exclusively on E/M services, and thus for which Attributed beneficiaries are not a subset of the Attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M service. To date we have implemented this alternative approach for four Advanced APMs:

- Bundled Payments for Care Improvement Advanced Model.
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track).
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement).
- Maryland Total Cost of Care Model (Care Redesign Program).

We have published links to the methodologies we use to identify Attribution-eligible beneficiaries for these Advanced APMs in the ''2023 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1509/2023%20Learning%20Resources%20for%20QP%20Status%20and%20APM%20Incentive%20Payment.zip.*

We adopted the general rule with flexibility to apply alternative methods for this criterion to ensure that, for the Advanced APMs for which attribution is based on services other than E/M services, the Attributed beneficiary population is truly a subset of such Advanced APMs' attribution-eligible populations and, ultimately, so that our way of identifying beneficiaries for purposes of Threshold Score calculations for QP determinations is appropriate for such Advanced APMs. That said, our thinking at the time that we developed these approaches was shaped by the form and nature of the Advanced APMs that existed at that time. A key lesson we have learned over time as we have implemented the APM track of the Quality Payment Program is that, by affording sufficient flexibility within the program, we can both foster innovation in Advanced APMs and simplify our execution of the program. By having a more narrowly-defined default approach to beneficiary attribution (relying on E/M services), we frequently needed to exercise the flexibility to determine an appropriate attribution methodology for an Advanced APM that falls into the exception, which meant that we identified several individually-tailored ways of performing the attribution methodology for each specific Advanced APM. As such, we have come to believe that application of our current regulations may result in increased complexity over time if, as we anticipate, Advanced APMs continue to evolve and use novel approaches to value-based care that may emphasize a broad range of covered professional services.

Further, as we noted in our discussion of the proposal to calculate QP status at the individual NPI level, primary care practitioners generally furnish a higher proportion of E/M services to beneficiaries than do specialists, and as for the Threshold Score calculations described previously, the emphasis on E/M services in our beneficiary attribution policy may have inadvertently encouraged APM Entities to exclude specialists from their Participation Lists. Under our current policy, if one or more eligible clinicians on the APM Entity's Participation List are furnishing covered professional services to a beneficiary but none of those services are among the E/M

services we use for attribution, that beneficiary would not be Attribution-eligible, and therefore, would not be included in our QP determination calculation at all, even though they actually are receiving covered professional services from an eligible clinician on the APM Entity's Participation List.

We are proposing to change the definition of ''Attribution-eligible beneficiary'' at § 414.1305 so that a single definition using covered professional services will be applied regardless of the Advanced APMs in which the eligible clinician participates. We believe that this complements our proposal to no longer conduct APM Entity group-level QP determinations and switch to making QP determinations at the individual eligible clinician level. We are also concerned that retention of the current policy under which E/M services are the default basis for attribution and special processes are required for Advanced APMs that use a different attribution basis could result in a complex set of unique attribution approaches for Advanced APMs.

In order to create a uniform basis for beneficiary attribution across all Advanced APMs, we are proposing to modify the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination. By no longer specifying E/M services as the default attribution basis in the sixth criterion, we also eliminate the need for flexibility to use a different attribution basis that ties attribution-eligibility to a specific Advanced APM's attribution methodology. This would simplify and streamline the attribution methodology by making attribution based on covered professional services across all Advanced APMs.

The proposal to base attribution eligibility on the receipt of a covered professional service also would address the issue discussed earlier in this section whereby, under our current policy, beneficiary attribution for purposes of QP determinations is contingent upon the beneficiary receiving an E/M services, and as a result beneficiaries who are actually being provided covered professional services by eligible clinicians on an APM Entity's Participation List are not Attribution-eligible if none of the services provided are E/M services. Under our proposal, because we would consider all covered professional services for attribution, and not solely E/M services, we would be able to include as Attributed beneficiaries those who are receiving only other (non-E/M) covered professional services through the Advanced APM. We believe this proposal would result in a QP calculation that, by including beneficiaries receiving any covered professional service, more accurately reflects eligible clinicians' actual participation in Advanced APMs.

We note that the proposal would not change the dates of service used for purposes of QP determinations. As such, QP determinations at any given snapshot date (March 31, June 30, and August 31, respectively) would be made by including all covered professional services furnished during the QP Performance Period for January 1 through the applicable snapshot date.

We believe that this change would more appropriately recognize the Advanced APM participation of the eligible clinicians for whom these determinations are being made, particularly when considered in conjunction with the proposal to make QP determinations at the individual eligible clinician level. We further believe that this proposal would simplify and streamline QP determinations, and address the challenges to Advanced APM participation reportedly faced by specialists who are less likely than primary care practitioners to provide E/M services.

We seek comment on this proposal to modify the sixth criterion in the definition of ''Attribution-eligible beneficiary'' at § 414.1305 to include a beneficiary who has a minimum of one claim for a covered professional service furnished by an eligible clinician who is on the Participation List for the APM Entity at any determination date during the QP Performance Period.

(4) QP Thresholds and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019 (performance year 2017). The All-Payer Combination Option, through which QP status is calculated using the Medicare Option as well as an eligible clinician's participation in Other Payer Advanced APMs, has been applicable since payment year 2021 (performance year 2019). In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b).

Section 4111(a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) amended section 1833(z)(2) of the Act by extending for payment years 2024 and 2025 (performance years 2022 and 2023) the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, section 4111(a)(2) of the CAA, 2023, amended section 1833(z)(2) of the Act to continue the QP payment amount thresholds that applied in payment year 2024 (performance year 2022) to payment year 2025 (performance year 2023). Additionally, section 4111(a)(2) of the CAA, 2023, amended section 1833(z)(2) of the Act to require that, for payment year 2025, the Secretary use the same percentage criteria for the QP patient count threshold that applied in payment year 2022. As such, the Medicare Option QP thresholds for payment year 2025 will remain at 50 percent for the payment amount method and 35 percent for the patient count method. The CAA, 2023, also amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2025 the Partial QP thresholds that were established since payment year 2021 under the Medicare Option. Therefore, the Partial QP thresholds for payment year 2025 (performance year 2023) will remain at 40 percent for the payment amount method and 25 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for payment year 2025 (performance year 2023) will be 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for payment year 2025 will be 40 percent for the payment amount method and 25 percent for the patient count method. In order to become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain minimum threshold percentages under the Medicare Option. For payment year 2025 (performance year 2023), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option to become a QP is 25 percent for the payment amount method or 20 percent under the patient count method. For Partial QP status, the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 20 percent

for the payment amount method or 10 percent under the patient count method.

To conform our regulation with the amendments made by the CAA, 2023, we propose to amend § 414.1430 by revising paragraphs (a) and (b) to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count under the Medicare Option and the All-Payer Option with respect to payment year 2025 (performance year 2023) in accordance with the CAA, 2023 amendments.

The proposed revisions to § 414.1430(a) and (b) for the Medicare Option and All-Payer Combination Option QP and Partial QP thresholds are as follows:

- Paragraph (a)(1)(iv) to state that for 2025 the amount is 50 percent, and paragraph (a)(1)(v) to state that for 2026 and later, the amount is 75 percent.
- Paragraph (a)(2)(iv) to state that for 2025 the amount is 40 percent, and paragraph (a)(2)(v) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (a)(3)(iv) to state that for 2025 the amount is 35 percent, and paragraph (a)(3)(v) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (a)(4)(iv) to state that for 2025 the amount is 25 percent, and paragraph (a)(4)(v) to state that for 2026 and later, the amount is 35 percent.
- Paragraph (b)(1)(i)(A) to state that for 2021 through 2025 the amount is 50 percent, and paragraph (b)(1)(i)(B) to state that for 2026 and later, the amount is 75 percent.
- Paragraph (b)(2)(i)(A) to state that for 2021 through 2025 the amount is 40 percent and paragraph (b)(2)(i)(B) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (b)(3)(i)(A) to state that for 2021 through 2025 the amount is 35 percent, and paragraph (b)(3)(i)(B) to state that for 2026 and later, the amount is 50 percent.
- Paragraph (b)(4)(i)(A) to state that for 2021 through 2025 the amount is 25 percent, and paragraph (b)(4)(i)(B) to state that for 2026 and later, the amount is 35 percent.

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TABLE 53: QP Threshold Score Updates

Medicare Option - Payment Amount Method				
Performance year / Payment Year	2021/2023 (Percent)	2022/2024 (Percent)	2023/2025 (Percent)	2024/2026 and later (Percent)
QP Payment Amount Threshold	50	50	50	75
Partial QP Payment Amount Threshold	40	40	40	50

Medicare Option - Patient Count Method				
Performance year / Payment Year	2021/2023 (Percent)	2022/2024 (Percent)	2023/2025 (Percent)	2024/2026 and later (Percent)
QP Patient Count Threshold	35	35	35	50
Partial QP Patient Count Threshold	25	25	25	35

All-Payer Combination Option - Payment Amount Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

All-Payer Combination Option - Patient Count Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

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(5) APM Incentive Payment

Prior to amendments made by the CAA, 2023, section 1833(z)(1) of the Act provided for APM Incentive Payments for eligible clinicians who are QPs with respect to a year in each payment year from 2019 through 2024. Specifically, for each of the specified payment years, in addition to the amount of payment that would otherwise be made for covered professional services furnished by an eligible clinician who is a QP for such year, there is an additional lump sum APM Incentive Payment equal to 5 percent of the eligible clinician's estimated aggregate payment amounts for such covered professional services for the preceding year (which we defined as the ''base year''). Covered professional services is defined at § 414.1305, with reference to the statutory definition at section 1848(k)(3) of the Act, as services for which payment is made under, or based on, the PFS and which are furnished by an eligible clinician (physician; practitioner as defined in section 1842(b)(18)(C) of the Act; PT, OT, or speech-language pathologist; or qualified audiologist as defined under section 1861(ll)(4)(B) of the Act).

In the CY 2017 Quality Payment Program final rule (81 FR 77445), we established a policy that, beginning with the 2017 QP Performance Period, the QP Performance Period would be the calendar year that is 2 calendar years before the payment year for the APM Incentive Payment. Thus, we established that the first QP Performance Period would begin on January 1, 2017, the first ''base year'' (established at 81 FR 77481 and 77482) for which we would use claims for professional services to calculate the 5 percent APM Incentive Payment amount would be in 2018, and the first payment year for the APM Incentive Payment would be in 2019 as required by the statute. Under our previously finalized policies, the QP Performance Period, base year, and payment year continue in this fashion on a rolling basis through payment year 2024, which was the final year for which the statute authorized an APM Incentive Payment. In the CY 2023 PFS final rule (87 FR 70114 through 70116), we explained that, beginning in payment year 2025, which correlates with performance year 2023, the statute did not provide for any type of payment incentive for eligible clinicians who become QPs.

Section 4111(a) of the CAA, 2023 amended section 1833(z)(1) of the Act to provide that eligible clinicians who are QPs with respect to payment year 2025 (performance year 2023) will receive an APM Incentive Payment equal to 3.5 percent of their estimated aggregate payment amounts for Medicare Part B covered professional services in the preceding year. In effect, this statutory change extends the APM Incentive Payment for one additional year, at a new percentage of 3.5 percent rather than 5 percent.

Accordingly, we propose to incorporate the change made by the CAA, 2023, by amending the regulation text at § 414.1450 to add the payment year 2025 APM Incentive Payment amount of 3.5 percent of covered professional services payments. We propose to amend paragraph (b)(1) to state that the amount of the APM Incentive Payment for payment years 2019 through 2024 is equal to 5 percent and, for payment year 2025, 3.5 percent, of the estimated aggregate payments for covered professional services furnished during the calendar year immediately preceding the payment year.

We also note that the CAA, 2023, did not extend the APM Incentive Payment beyond payment year 2025. Beginning for the 2026 payment year, which relates to the 2024 QP Performance Period, section 1848(d)(1)(A) of the Act specifies that there shall be two separate PFS conversion factors, one for items and services furnished by a QP, and the other for other items and services (the nonqualifying APM conversion factor). Each conversion factor will be equal to the conversion factor for the previous year multiplied by the applicable update specified in section 1848(d)(20) of the Act. The update specified for the conversion factor for QPs will be 0.75 percent, while the update for all others will be 0.25 percent.

(6) Targeted Review of QP Determinations

In the CY 2021 PFS final rule (85 FR 84952), we finalized a policy to provide an opportunity for eligible clinicians to bring to our attention potential clerical errors we have may made that could have resulted in the omission of an eligible clinician from a Participation List used for purposes of QP determinations, and for us to review and make corrections if warranted. We also finalized that, after the conclusion of the time period for targeted review, there would be no further review of our QP determination with respect to an eligible clinician for the QP Performance Period. We noted that, consistent with section 1833(z)(4) of the Act, and as provided under § 414.1455(a) of our regulations, there is no right to administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the determination that an eligible clinician is a QP or Partial QP under § 414.1425, or of the determination of the amount of the APM Incentive Payment under § 414.1450.

In the CY 2021 PFS final rule (85 FR 84953), we finalized our proposal to align the timing and procedures for this targeted review process with the MIPS targeted review process as codified at § 414.1385. We noted this alignment would reduce the likelihood of confusion and burden on eligible clinicians and APM Entities.

In light of the transition in incentives for eligible clinicians who are QPs for a year, as provided in statute, from an APM Incentive Payment to the differentially higher PFS conversion factor beginning with the 2024 QP performance period and 2026 payment year, we are proposing at section IV.A.4.j. of this proposed rule to adjust the Targeted Review period in order to meet operational timelines to ensure that we can meet statutory requirements for the application of the differential conversion factors, and the resulting differential PFS payment rates, to eligible clinicians who are, and are not, QPs for the year. As discussed in section IV.A.4.j. of this proposed rule, we believe that adjusting the Targeted Review period will enable us to meet our statutory obligation to apply the differentially higher QP conversion factor beginning on January 1 of each payment year beginning with CY 2026. We encourage readers to review section IV.A.4.j. of this proposed rule.

n. Advanced APMs

(1) General Overview

In this section, we address policies regarding several aspects of the Advanced APM criterion for CEHRT use at § 414.1415(a). We are proposing to amend the definition of CEHRT at § 414.1305 that would apply to Advanced APM participants, and modify the Advanced APM CEHRT use criterion at § 414.1415(a) to recognize the CEHRT that is relevant to the clinical practice of participants in the Advanced APM.

We believe the Quality Payment Program must be responsive to, and supportive of, innovation in technology and in provider organization. It is our goal to encourage not only provider ownership of this technology, but full adoption and integration of the most advanced health information technology (health IT) into clinical practice. We developed these proposals to modify the CEHRT that is required for Advanced APMs with this goal in mind, and we will continue to monitor advancements

and opportunities in the health IT space to better prepare and align our program and APMs with the most cutting-edge technologies and innovative provider arrangements, for the benefit of eligible clinicians participating in APMs, and the Medicare beneficiaries we serve.

(2) Background

(a) Advanced APM CEHRT Use Criterion

Under section 1833(z)(3)(D)(i)(I) of the Act, Advanced APMs are those APMs that require participants to use CEHRT. We codified this CEHRT use criterion for Advanced APMs at § 414.1415(a)(1). As such, the CEHRT use criterion under § 414.1415(a)(1) states that, to be an Advanced APM, the APM must require at least a certain percentage of eligible clinicians in each APM Entity participating in the APM, or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers. In the CY 2017 Quality Payment Program final rule, we specified at § 414.1415(a)(1)(i) that an Advanced APM is one that requires at least 50 percent of eligible clinicians in each APM Entity to use CEHRT to document and communicate clinical care to their patients or health providers (81 FR 77410). In the CY 2019 PFS final rule (83 FR 59918), we amended § 414.1415(a)(1) to increase the required percentage from 50 percent to 75 percent.

(b) Definition of CEHRT

Section 1848(o)(4) of the Act defines CEHRT as a qualified electronic health record (as defined in section 3000(13) of the Public Health Service Act, or PHSA) that is certified by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to section 3001(c)(5) of the PHSA in accordance with the certification standards that ONC adopted under section 3004 of the PHSA.

In implementing the definition of CEHRT at § 414.1305 for the MIPS track of the Quality Payment Program, we adopted the definition of CEHRT used for the Medicare EHR Incentive Program (also known as ''Meaningful Use'') at § 495.4 (81 FR 77211 through 77213). In the CY 2017 Quality Payment Program final rule, we explained that we intended ''to maintain continuity for MIPS eligible clinicians and health IT vendors who may already have CEHRT or who have begun planning for a transition to technology certified to the 2015 Edition based on the definition of CEHRT finalized for the EHR Incentive Programs in the 2015 EHR Incentive Programs final rule'' and ''to maintain consistency with the EHR Incentive Programs CEHRT definition at 42 CFR 495.4'' (81 FR 77212).

For the Advanced APM track of the Quality Payment Program, we in turn adopted the definition of CEHRT for MIPS under § 414.1305 (81 FR 77409 through 77410). We explained that applying the same definition of CEHRT for purposes of both the MIPS and Advanced APM tracks of the Quality Payment Program would reduce administrative costs and confusion among clinicians and maintain consistency across programs, permitting clinicians to use shared CEHRT systems to participate in either MIPS or Advanced APMs (81 FR 77409 through 77410).

Consequently, the MIPS and Advanced APM tracks of the Quality Payment Program share the same definition of CEHRT at § 414.1305. Since the CY 2019 performance period, this has generally meant EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and that has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition of CEHRT at § 414.1305. The currently applicable definition of CEHRT at § 414.1305 specifically requires that the EHR technology has been certified to the following 2015 Edition health IT certification criteria: (1) family health history at 45 CFR 170.315(a)(12); (2) patient health information capture at 45 CFR 170.315(e)(3); and (3) as necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including applicable measure calculation certification criteria at 45 CFR 170.315(g)(1) or (2) and clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) (and optionally (c)(4)) and can be electronically accepted by CMS.

Because our definition of CEHRT at § 414.1305 ultimately derives from the definition of CEHRT used for the Meaningful Use Program, our Advanced APMs have required their participants to use CEHRT that is capable of meeting all requirements of a qualified EHR. As such, Advanced APMs generally require participants to use CEHRT that meets requirements for 2015 Edition Base EHR (as defined at 45 CFR 170.102); all requirements of Meaningful Use set forth in section 1848(o)(2) of the Act; and all requirements for reporting on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. When we adopted the same definition of CEHRT at § 414.1305 for purposes of MIPS and Advanced APMs in the CY 2017 Quality Payment Program final rule, we acknowledged that such a policy may include some requirements not directly applicable to the APM Entities' practice. Specifically, we stated at that time that ''we understand this proposed CEHRT definition may include some EHR functionality used by MIPS eligible clinicians which may be less relevant for an APM participant and likewise APM participants may use additional functions that are not required for MIPS participation'' (81 FR 77409). At the time, we reasoned that ''using the same CEHRT definition for both MIPS and Advanced APMs would allow eligible clinicians to continue to use shared EHR systems and give eligible clinicians flexibility of participation as a MIPS eligible clinician or an eligible clinician in an Advanced APM without needing to change or upgrade EHR systems'' (81 FR 77409).

Although we acknowledged that this CEHRT definition may impose more rigorous requirements on APM participants than necessary, we nonetheless maintained that ''we generally want APMs to retain the flexibility to require activities performed using CEHRT that may vary from those prescribed under the advancing care information performance category in MIPS'' (81 FR 77412).[327] We also recognized that aligning the CEHRT definition for Advanced APMs with MIPS ''would go beyond what the statute requires'' (81 FR 77412). When we adopted the CEHRT definition for MIPS and Advanced APMs, one commenter suggested that our proposed CEHRT criterion for Advanced APMs was narrow, and that ''a strong, broad health IT infrastructure should be a key element used to identify Advanced APMs rather than the narrow proposed CEHRT criteria'' (81 FR 77410). We

[327] Section 1848(q)(2)(A)(iv) and (B)(iv) of the Act requires that the Secretary assess MIPS eligible clinicians' performance with respect to the ''meaningful use of certified EHR technology'' in accordance with the requirements set forth at section 1848(o)(2) of the Act as one of the four performance categories for MIPS. In the CY 2017 Quality Payment Program final rule, we named this required MIPS performance category the ''advancing care information performance category.'' (81 FR 77010). We have since renamed this MIPS performance category, requiring the meaningful use of CEHRT, as the ''Promoting Interoperability performance category.'' (85 FR 84820 through 84821).

agreed that ''Advanced APMs need a strong health IT infrastructure as a foundation for communicating and delivering comprehensive and coordinated care to their patients,'' but at that time we wanted to prioritize continuity between the two tracks of the Quality Payment Program to maximize flexibility for eligible clinicians. However, we indicated that we would be prepared to update this definition as needed in the future.

(3) Proposal To Update CEHRT Definition and CEHRT Use Criterion for Advanced APMs

After several years of experience with the uniform definition of CEHRT for purposes of MIPS and Advanced APMs, and based on input we have received from interested parties, we now believe that the standard for CEHRT use for Advanced APMs may have been unnecessarily burdensome, imposing unwarranted barriers to organization of and participation in Advanced APMs, and not clinically relevant for many prospective and current participants in Advanced APMs. As previously discussed, our policy at § 414.1415(a)(1)(i) currently requires that at least 75 percent of eligible clinicians in each participating APM entity group, and each hospital that are APM Entities, to use CEHRT, as defined in § 414.1305, to document and communicate clinical care to their patients or health care providers. By referring in the Advanced APM CEHRT use criterion to CEHRT, as defined in § 414.1305, Advanced APMs required participants to adopt and implement health IT that is capable of meeting all requirements of a qualified EHR, which means CEHRT that meets all requirements for 2015 Edition Base EHR (as defined at 45 CFR 170.102); all requirements of Meaningful Use set forth in section 1848(o)(2) of the Act; and all requirements for reporting on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. We have heard from many interested parties that our requirements for use of CEHRT are falling short of some of our intended goals. Specifically, we have heard from many interested parties that our current requirements for use of CEHRT have led Advanced APMs to apply an inflexible standard that does not allow them to take into account whether certain CEHRT modules are relevant for, and applicable to, the specific clinical practice areas of their intended or actual participants. By placing a broad set of requirements for use of CEHRT, particularly regarding the criteria the health IT must be certified as meeting to satisfy our definition of CEHRT at § 414.1305, interested parties report that we are needlessly burdening some potential and actual APM participants because they must adopt health IT modules that are not always clinically relevant across provider types that would participate in an Advanced APM. Specifically, interested parties noted that our requirement that Advanced APMs must require participants to use health IT certified as meeting criteria necessary to report on objectives and measures of the MIPS Promoting Interoperability performance category, even when such health IT is not clinically relevant for or applicable to APM participants' practice, is needlessly burdensome and a barrier to innovation and participation in APMs. To support their position, interested parties noted as an example, that application of our current Advanced APM CHERT use criterion and associated CEHRT definition has required specialists in the Kidney Care Choices (KCC) Model or providers in the ACO Realizing Equity, Access, and Community Health (REACH) Model to purchase certified Health IT Modules beyond those required as part of the 2015 Edition Base EHR definition at 45 CFR 170.102 that are not immediately necessary or applicable to their clinical practice.

We have learned that Advanced APMs have not had the flexibility to require certified health IT that is tailored to their specific participants' practice areas. Likewise, we could envision a scenario where, to achieve Advanced APM status under our current policy, an APM or APM Entity would exclude from participation specialists or other eligible clinician types, such as pathologists, for whom compliance with our current CEHRT requirements beyond the Base EHR definition would be burdensome and beyond the scope of their typical practice, even though participation of such eligible clinicians would be relevant and beneficial to the goals of the APM.

For Advanced APMs, we believe that it is important both to apply a rigorous standard for use of CEHRT and to allow sufficient flexibility to Advanced APMs to specify CEHRT modules that are clinically relevant for their participants. We believe that our current CEHRT use requirements meet the former goal (application of a rigorous standard), but not the latter (allowing sufficient flexibility).

Further, our current CEHRT use criterion specifies that 75 percent of participants in the APM must use CEHRT as defined in § 414.1305, and allows for 25 percent of participants to not have or use CEHRT. This policy establishes a minimum percentage of Advanced APM participants must use CEHRT, but without consideration of which eligible clinicians in each participating APM Entity (or hospital) must use CEHRT, or whether it is clinically appropriate for any of those eligible clinicians to not use CEHRT. As such, this policy could allow eligible clinicians who could and should be using CEHRT to forego CEHRT use solely because enough of their colleagues are using CEHRT to meet the requirement of the Advanced APM. Additionally, we have heard from interested parties that, for most Advanced APM participants, CEHRT use among eligible clinicians is close to 100 percent. Given this information and the fact that the 70 percent CEHRT use standard has been in effect for almost five years, we believe it would be appropriate to re-evaluate our approach to the application of the CEHRT use requirement to Advanced APMs and their participants. We want to maintain the rigor of our CEHRT use criterion for Advanced APMs while providing Advanced APMs flexibility to require CEHRT use that is applicable for the practice areas of their participants and their eligible clinicians. Further, we believe any exceptions to CEHRT use that are permitted under the Advanced APM should be based on clinical appropriateness, rather than on generalized application of percentages.

First, we are proposing to amend the definition of CEHRT at § 414.1305 by adding a new paragraph (3) to specify that, for purposes of the Advanced APM criterion under § 414.1415(a)(1), beginning with CY 2024, CEHRT means EHR technology certified under the ONC Health IT Certification Program that meets: (1) the 2015 Edition Base EHR definition, or any subsequent Base EHR definition (as defined in at 45 CFR 170.102); and (2) any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice areas involved, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM.

We believe our proposal to update the definition of CEHRT for Advanced APMs at § 414.1305 would provide flexibility to each APM to determine what CEHRT functionalities are relevant to the model and its participant APM

Entities and eligible clinicians. We believe that providing Advanced APMs with the greater flexibility permitted by the statute with respect to requiring CEHRT use will foster innovation in model design and diversity in APM participation. Specifically, we believe our proposed amendment to the CEHRT definition at § 414.1305 will facilitate innovation in APM design, and enable a broad range of participants and their eligible clinicians to meet Advanced APM CEHRT use requirements by adopting health IT that satisfies the 2015 Edition Base EHR definition at 45 CFR 170.102 and is certified as meeting other ONC health IT certification criteria adopted, or updated in 45 CFR 170.315, as is clinically relevant to their practice, without unnecessarily obtaining other health IT, such as the health IT necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category.

We note that participation in an Advanced APM does not automatically exclude eligible clinicians from MIPS. Eligible clinicians in an Advanced APM who do not achieve Qualifying APM Participant (QP) status or Partial QP status, or who are not otherwise exempt from MIPS, are subject to MIPS reporting requirements and the MIPS payment adjustment. Our proposed amendment to the CEHRT definition under paragraph (3) at § 414.1305 for Advanced APMs has limited effect upon the requirement to participate in MIPS if QP or Partial QP status is not achieved. Accordingly, under our proposal, eligible clinicians in Advanced APMs would still need to be prepared to report to MIPS, including using CEHRT as necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, in the event that they do not achieve QP or Partial QP status.

In section IV.A.4.f.(4) of this proposed rule, we are also proposing other modifications to the CEHRT definition at § 414.1305 to be more flexible in reflecting any changes ONC may make to its Base EHR definition, certification criteria, and other standards for health IT at 45 CFR part 170. Our proposed amendment to the CEHRT definition under paragraph (3) at § 414.1305 for Advanced APMs is consistent with our other proposed amendments as set forth in section IV.A.4.f.(4) of this proposed rule.

Second, we are proposing to amend our current Advanced APM CEHRT use criterion at § 414.1415(a)(1). Specifically, we propose to amend the regulation to end the current 75 percent CEHRT use requirement at § 414.1415(a)(1)(i) with the CY 2023 QP performance period. Then we propose to add a new paragraph at § 414.1415(a)(1)(iii) to specify that, to be an Advanced APM, the APM must require all eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the participants, each hospital, to use CEHRT that meets our proposed new paragraph (3) of the CEHRT definition at § 414.1305. In essence, we are proposing to no longer specify a minimum number of eligible clinicians that an Advanced APM must require to use CEHRT, and instead, simply specify that the Advanced APM must require all participating eligible clinicians to use CEHRT that meets our proposed modified, and more flexible, definition. We are also proposing to revise § 414.1415 by making non-substantive technical edits to paragraphs (a)(1)(i) and (a)(1)(ii) to improve clarity.

This proposal is consistent with section 1833(z)(3)(D)(i)(I) of the Act, which generally requires that Advanced APMs require their participants to use CEHRT as defined in section 1848(o)(4) of the Act. We believe this proposed amendment to the Advanced APM CEHRT use criterion will further enhance innovation in Advanced APM development and diversity in participation, allowing for novel APM Entity compositions, because Advanced APM participants will no longer have to concern themselves with what percentage of eligible clinicians meet our current CEHRT requirements. We further believe that, under our more flexible proposed CEHRT definition and Advanced APM CEHRT use criterion, Advanced APMs could create their own CEHRT use requirements, potentially beyond what we currently require, tailored to the various types of clinicians and practice areas the Advanced APM intends to include in its model. We believe our proposal would permit Advanced APMs to recruit and retain participants that represent a variety of practice types, and to require different types of EHR technologies certified under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, or subsequent Base EHR definition, at 45 CFR 170.102 and additional ONC health IT certification criteria adopted and updated in 45 CFR 170.315 as specifically applicable to different types of clinical practice.

We seek comment on this proposal.

(4) All Payer Advanced APMs

In the CY 2017 Quality Payment Program final rule (81 FR 77459), we proposed policies, effective beginning for performance year 2021, that would allow eligible clinicians to earn QP status through participation in a combination of payment arrangements designed and implemented by Other Payers and Medicare Advanced APMs. The statute includes a CEHRT use criterion for Other Payer Advanced APMs as it does for Medicare Advanced APMs, and we finalized the same CEHRT use criterion for Other Payer Advanced APMs as for Medicare Advanced APMs (81 FR 77463). Likewise, in this rule, we are proposing to amend the Other Payer Advanced APM criteria at § 414.1420(b) to conform to the changes we now propose for the Medicare Advanced APMs, and to be reflected in amendments to § 414.1415(a)(1)(i), to remove the 75 percent minimum CEHRT use requirement for Advanced APMs and replace it with a more flexible CEHRT use requirement based on our proposed revised definition of CEHRT for purposes of Advanced APM determinations. We are also proposing to revise § 414.1420(b) by making additional non-substantive technical edits to improve clarity.

The changes we are proposing for Medicare Advanced APMs are designed to require use of technologically sufficient EHRs, while affording Advanced APMs the ability to tailor additional CEHRT use requirements to those features or capabilities that are clinically relevant to the APM and its participants. We believe that this same flexibility should be afforded in the context of Other Payer Advanced APMs. The All Payer Combination Option through which we consider the participation of eligible clinicians in Other Payer Advanced APMs offers an additional pathway to achieve QP status for eligible clinicians participating in both Medicare Advanced APMs and Other Payer Advanced APMs. Under the All Payer Combination Option, we consider the combined participation of eligible clinicians in Medicare and Other Payer Advanced APMs. Similar to the statutory CEHRT use requirement for Advanced APMs under section 1833(z)(3)(D)(i)(I) of the Act, section 1833(z)(2)(iii)(II)(bb) of the Act specifies that Other Payer Advanced APMs are those under which CEHRT is used. Since the All Payer Combination Option for QP determinations involves the same eligible clinician participants as the Medicare Option, and considers participation in both Medicare Advanced APMs and Other Payer Advanced APMs, we believe we should continue to apply the same CEHRT use

standard for both Medicare and Other Payer Advanced APMs. Further, we believe the same need exists for flexibility in the CEHRT that is required to be used in Other Payer Advanced APMs. This would allow Other Payer Advanced APMs to structure their CEHRT use requirements to be clinically relevant to the APM and participating eligible clinicians, and avoid the need to obtain clinically unnecessary technology simply for purposes of meeting what we now believe to be an overly restrictive CEHRT use criterion.

We seek comment on this proposal.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment (see section VI. of this proposed rule) on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

Private Sector: To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2022/oes_nat.htm*). In this regard, Table 54 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 54: National Occupational Employment and Wage Estimates (Excluding Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43-3021	21.54	21.54	43.08
Business Operations Specialists	13-1000	40.04	40.04	80.08
Computer System Analysts	15-1211	51.70	51.70	103.40
Financial Specialists	13-2000	44.37	44.37	88.74
General and Operations Manager	11-1021	59.07	59.07	118.14
Licensed Practical and Licensed Vocational Nurses	29-2061	26.86	26.86	53.72
Medical and Health Services Managers	11-9111	61.53	61.53	123.06
Secretaries and Administrative Assistants	43-6014	20.87	20.87	41.74

For our purposes, BLS' May 2022 National Occupational Employment and Wage Estimates does not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we are using an average conglomerate wage of $274.44/hr as demonstrated below in Table 55.

TABLE 55: National Occupational Employment and Wage Estimates (Physicians)

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	145.66	145.66	291.32
Family Medicine Physicians	29-1215	107.91	107.91	215.82
General Internal Medicine Physicians	29-1216	108.30	108.30	216.60
Obstetricians and Gynecologists	29-1218	133.33	133.33	266.66
Orthopedic Surgeons, Except Pediatric	29-1242	178.56	178.56	357.12
Pediatric Surgeons	29-1243	174.51	174.51	349.02
Pediatricians, General	29-1221	97.71	97.71	195.42
Physicians, All Other	29-1229	114.76	114.76	229.52
Psychiatrists	29-1223	118.92	118.92	237.84
Surgeons	29-1240	162.49	162.49	324.98
Surgeons, All Other	29-1249	167.25	167.25	344.50
Total				3,018.80
Average Physician Wage (3,018.80/11)				274.44

Beneficiaries: We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $21.98/hr.

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices [328] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $1,059 [329] for 2022, divided by 40 hours to calculate an hourly pre-tax wage rate of $26.48/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.50/hr ($26.48/hr x 0.17), resulting in the post-tax hourly wage rate of $21.98/hr ($26.48/hr—$4.50/hr). Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

[328] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

[329] *https://fred.stlouisfed.org/series/LEU0252881500A.*

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (§ 414.940)

The following proposed changes will be submitted to OMB for review under control number 0938–1435 (CMS–10835).

As discussed in section III.A. of this proposed rule, as a part of implementing section 1847A(h) of the Act, as added by section 90004 of the Infrastructure Act, the Secretary is authorized to recognize, through notice and comment rulemaking, drugs with unique circumstances that justify an increase of the applicable percentage greater than 10 percent. In section III.A.3.d of this proposed rule, we are proposing modifications to § 414.940 to establish an application process for drug manufacturers to request an increased applicable percentage for an individual drug product based on its unique circumstances.

We are proposing that, to request we consider increasing the applicable percentage for a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage. Such justification could include documents, such as (but not limited to) a minimum vial fill volume study or a dose preparation study.

As discussed in section VII.E.4. of this proposed rule, our estimates show a projected 28 billing and payment codes meeting the definition of refundable single-dose container or single-use package drug with 10 percent or more discarded units, which is the applicable percentage specified in section 1847A(h)(3) of the Act. Therefore, we anticipate a similar number of drugs could owe a refund under section 90004 of the Infrastructure Act. Since 25 of those billing codes have an estimated annual refund obligation of over $50,000, we expect that, initially (that is, the first year the proposed application process is available), the manufacturers of those 25 drugs to submit an application for consideration of an increased applicable percentage based on unique circumstances.

Once a manufacturer has applied for a drug and a decision has been made regarding whether an increased applicable percentage is appropriate, the manufacturer would not need to apply again. Therefore, subsequent years we would expect a smaller number of applications. When evaluating the

approval dates of these 25 drugs, we find that there is a range of 0 to 4 drugs per year approved that would be expected to owe a refund of more than $50,000 per year. From 2010 through 2020, the mean number of such approvals is 1.45 per year. If rounded up, we estimate that we would typically receive 2 applications per subsequent to the initial application year.

We estimate that the burden per respondent/applicant of drafting and submitting the unique circumstance application to be 5 hours. As we anticipate 25 applications in the initial year that applications are available, we estimate a total burden of 125 hours (25 applications × 5 hr) per at a cost of $5,218 ($41.74/hr × 125 hr). For subsequent years, we estimate a total annual burden related to drafting and submission of 10 hours (2 applications × 5 hr per respondent/applicant) at an annual cost of $418 (41.74/hr × 10 hr).

2. ICRs Regarding the Clinical Laboratory Fee Schedule: Data Reporting by Laboratories

As described in section III.D of this proposed rule, under the Clinical Laboratory Fee Schedule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories,'' and we proposed to revise the regulations at § 414.504(a)(1) to account for a delay in reporting until January 1, 2024 through March 31, 2024. As stated in section 1834A(h)(2) of the Act, chapter 35 of title 44 U.S.C., which includes such provisions as the PRA does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out any proposed burden estimates under this section of the proposed rule. Please refer to section VII.E.7. of this proposed rule for a discussion of the impacts associated with the changes described in section III.D. of this proposed rule.

3. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out proposed Shared Savings Program burden estimates under this section of the preamble. Please refer to section VII.E.10. of this proposed rule for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.G. of this proposed rule.

4. ICRs Regarding the Updates to the Medicare Diabetes Prevention Program

In section III.L. of this proposed rule, we propose to extend specific Medicare Diabetes Prevention Program (MDPP) flexibilities allowed during the PHE for COVID–19 1135 waiver event by 4 years. In addition, we are proposing to update the MDPP payment structure to pay for beneficiary attendance on a fee-for-service basis while retaining the diabetes risk reduction performance payments. Finally, we are proposing to remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition as well as remove most references to, and requirements of, the Ongoing Maintenance Sessions given that eligibility for these services will end on December 31, 2023. We expect the proposed policies will increase the number of eligible organizations willing to enroll as MDPP suppliers. We also anticipate that the extended PHE flexibilities will make MDPP more marketable to both suppliers and beneficiaries due to the continued flexibility in how the MDPP set of services are delivered live, either in-person or virtually (or a combination of the two). We anticipate the proposed payment structure changes will motivate suppliers to retain participants due to more frequent payments. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the provisions.

5. Appropriate Use Criteria for Advanced Diagnostic Imaging

As discussed in section III.J. of this proposed rule, we are proposing to pause efforts to implement the Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services program for reevaluation and to rescind the current AUC program regulations at § 414.94. The program was established in the Protecting Access to Medicare Act of 2014 (PAMA) and we have used rulemaking over the ensuing years to stand up the program in phases while aiming for a clinically useful and least provider-burdensome approach. At this time, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we propose in section III.J. of this proposed rule to pause implementation of the AUC program for reevaluation, and rescind the current AUC program regulations from § 414.94.

The following collection of information requests would be affected by this rule's proposal to rescind the AUC program regulations from § 414.94: CMS–10570 (OMB 0938–1288), CMS–10624 (OMB 0938–1315), and CMS–10654 (OMB 0938–1345). Given that the AUC program regulations, which include these information collection requirements, would be rescinded, all three collections would no longer be needed.

CMS–10570 (OMB 0938–1288) relates to the application and qualification process for provider-led entities (PLEs). If we finalize the proposal and rescind the current regulations at § 414.94, then we will discontinue this collection of information. The following table scores the impact of discontinuing the requirements and burden that are currently active and approved by OMB under the aforementioned control number, showing an expected 10 re-applications per year. We note however, that because we received less than 10 applicants in each year 2017–2022, there have been and will continue to be fewer than 10 re-applicants each year. In fact, the number of PLEs has overall decreased as qualified PLEs exit the program, choosing not to re-apply. In 2022 we expected all seven PLEs approved in 2017 to reapply; however, only two submitted re-applications and were re-qualified. For 2023, we froze the re-application process, continuing the approval of the three PLEs that had initially qualified in 2018. If we were not proposing to pause the AUC program and rescind the current regulations at § 414.94, then we would expect one re-application in 2024 and no re-applications in 2025.

At the time of the last approval in 2021, we expected the burden for PLEs re-applying for qualification to be half the burden of the initial application process. In the explanation below, we continue to use the previously approved number of responses, respondents and time, while updating the labor cost to reflect May 2022 BLS wages. As previously estimated, the PLEs would be able to make modifications to their original application which should result in a burden of 10 hours at $80.08/hr for a business operations specialist (occupation code 13–100) to compile, prepare and submit the required information, 2.5 hours at $123.06/hr for a medical and health services manager

(occupation code 11–911) to review and approve the submission, and 2.5 hours at $242.3/hr for a physician (occupation code 29–1210) to review and approve the submission materials. Annually, we estimate 15 hours per submission at a cost of $1,714.2 per organization. In aggregate, we estimate 150 hours (15 hr × 10 submissions) at $17,142 ($1,714 × 10 submissions).

TABLE 56: Burden of Pausing AUC Program Implementation Efforts for Reevaluation and Rescinding § 414.94

Regulation Section(s)	Respondents	Total Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
§ 414.94(c)(2) (reapplication)	(10)	(10)	(15)	(150)	(1,714.2)	(17,142)

CMS–10624 (OMB 0938–1315) relates to the application and qualification process for Clinical Decision Support Mechanisms (CDSMs). This collection of information is no longer active. CMS–10624 was first approved on March 6, 2017, and was associated with the CY 2017 Physician Fee Schedule final rule (November 15, 2016; 81 FR 80170). CMS–10624 last expired on March 31, 2020. In June 2020, CMS filed a request to discontinue CMS–10624 (OMB 0938–1315).

CMS–10654 (OMB 0938–1345) relates to the consultation of AUC through a qualified CDSM by an ordering professional or clinical staff acting under the direction of the ordering professional. While this collection of information is no longer active, the impact of discontinuing the requirements and burden is addressed in this proposed rule RIA (*see* section VII. Regulatory Impact Analysis of this proposed rule).

6. ICRs for Medicare Provider and Supplier Enrollment

None of this rule's Medicare and Medicaid provider enrollment provisions propose any new, revised, or removed information collection requirements or burden. Regarding the proposal to reduce the timeframe for reporting practice location changes from 90 days to 30 days, this change would not alter the requirement for disclosing the change via the applicable Form CMS–855 or Form CMS–20134. It would only revise the timeframe in which the change must be reported. Hence, there would be no change in the ICR burden.

7. ICRs Regarding the Medicare Ground Ambulance Data Collection System (GADCS) (§ 414.626)

Section 1834(l)(17) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, we are not setting out any proposed burden estimates under this section of the rule.

8. ICRs Related to the Changes in the RHC/FQHC CfCs and Hospice CoPs

a. Permitting MFT and MHCs To Furnish Services in RHC/FQHCs

The following proposed changes will be submitted to OMB for review under control number 0938–0344 (CMS–R–38).

In section III.C. of this proposed rule, we implement section 4121 of the CAA by proposing conforming changes at § 491.8(a)(3) and (a)(6) that would add MFT and MHCs to the list of staff who may be the owner or an employee of the clinic or center or may furnish services under contract to the clinic or center as well as included as staff available to furnish patient care services at all times the clinic or center operates. If an RHC or FQHC provides services furnished by an MFT or MHC they would be required to update their patient care policy, as set out in section § 491.9(b)(2) of the CfCs.

The existing requirement at § 491.9(b)(2), *Patient care policies,* requires that policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners, with at least one member who is not a member of the clinic or center staff. The patient care policies must describe the services the clinic or center furnishes directly, through agreement or arrangement, guidelines for medical management of health problems, and rules for the storage, handling, and administration of drugs and biologicals.

As we are proposing to include MFTs and MHCs as professionals who can provide services in an RHC and FQHC, there will be a burden associated with the existing requirement at § 491.9(b)(3)(i). This requirement states that policies include ''A description of the services they provide directly or through agreement or arrangement.'' Therefore, if an RHC or FQHC provides services furnished by an MFT or MHC they must update their policies to include a description of the services provided.

We note that the time and effort required to conduct this activity will vary depending on if a clinic or center chooses to provide services furnished by an MFT or MHC. We also believe that some RHCs and FQHCs may already provide services furnished by an MFT or MHC. State Medicaid programs can cover ambulatory care services (including mental health and substance use disorder services) under a number of different mandatory Medicaid benefits such as outpatient hospital services, physician services, RHC and FQHC services, as well as optional benefits such as rehabilitative services, and services of other licensed practitioners.

The National Association of Community Health Center's 2017 policy assessment suggests that 21 State Medicaid programs cover services provided by MFTs, and 25 State Medicaid programs cover services provided by licensed professional counselors.[330] Due to approximately half of the State's Medicaid programs already covering services furnished by an MFT or MHC and the assumption that some centers and clinics will not

[330] *https://www.nachc.org/wp-content/uploads/2019/03/BH-Fact-Sheet-3.20.19.pdf.*

provide these services, we believe only 50 percent of RHCs and 50 percent of FQHCs will incur this burden. The total RHCs and FQHCs who will have to meet this 1-time burden is 2,643 clinics and 5,643 centers, or 8,286 combined.[331] [332]

Each clinic or center is required by the existing requirement at 491.9(b)(2) to have at least two clinical professionals (one physician/administrator at $229.52/hr and one advanced practice provider at $119.88/hr) reviewing and updating the policies. We estimate that it takes existing RHCs and FQHCs 4 hours every 2 years for clinical staff to review and make changes to all patient care policies. Based on this, we estimate that adding MFT and MHC services (as necessary) to the patient care policies would take approximately 15 minutes (.25 hr) for each clinical professional. In aggregate, we estimate an annual burden of 2,071.50 hours (0.25 hr × 8,268 RHC and FQHCs) at a cost of $361,891.05 [(1,035.75 hr × $229.52/hr) + (1,035.75 hr × $119.88/hr)].

TABLE 57: One-time Burden for Time Spent on Clinics or Centers Updating Patient Care Policies to Include a Description of MFT and MHC Services

Occupation	Hourly wage (a)	One-time hourly burden (b)	Number of clinics and centers (c)	Total time (d)=(b) x (c)	One-time cost estimate (a) x (d)	
Physician	$229.52	.25 hr	8,286		1035.75	$237,725.34
Advanced Practice Provider	$119.88	.25 hr	8,286		1035.75	$124,165.71
Total:	Varies				2071.50	$361,891.05

b. ICRs Related to Permitting MFTs and MHCs To Serve as Members of the Interdisciplinary Group (IDG) in Hospices (§ 418.56 and § 418.114)

In section III.O. of this proposed rule, we would implement subtitle C, section 4121 of the CAA 2023 by proposing conforming changes at § 418.56(a)(1)(iii) that would permit MFTs or MHCs, in addition to social workers, to serve as members of the IDG. The conforming change would require hospices to include at least one SW, MFT or MHC to serve as a member of the IDG. Hospices would have the flexibility to determine which discipline(s) are appropriate to serve on the IDG based on the needs of the patients. We believe that with the introduction of MHC and MFT into the hospice CoPs, it is important to include these new disciplines into the personnel qualifications at § 418.114.

In this rule we are also proposing to add both MFT and MHC to the provider requirements under 42 CFR subpart B (Medical and Other Health Services) at §§ 410.53 and 410.54. Therefore, to avoid duplication and confusion between the CoP and the provider requirements under the Medical and Other Health Services provision, we are proposing to add both MFT and MHC to the requirements at § 418.114(c)(3) and (4) and referencing the new requirement at §§ 410.53 and 410.54, respectively.

In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the proposed revisions to the requirements at §§ 418.56(a)(iii) and 418.114(c)(3) and (4) are exempt from the PRA. We believe permitting hospices the ability to select one of these disciplines (SW, MFT or MHC) to serve as a member of the IDG and the addition of both MFT and MHC to the personnel requirements with reference to the new requirement at §§ 410.53 and 410.54 respectively, is reasonable and customary business practice. We state such in the information collection request that is currently approved under OMB control number: 0938–1067 ((CMS–10277). Therefore, we are not proposing to seek OMB's approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to §§ 418.56(a)(1)(iii) and 418.114(c)(3) and (4), but we request public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary and this time and effort would be incurred by hospice staff even absent this regulatory requirement.

9. RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

Please note that this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all

[331] *https://qcor.cms.gov/active_nh.jsp?which=12&report=active_nh.jsp&jumpfrom=#pagetop.*

[332] *https://qcor.cms.gov/active_nh.jsp?which=11&report=active_nh.jsp&jumpfrom=#pagetop*

costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that we will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned.

10. Basic Health Program (BHP) Provisions

a. Proposed Information Collection Requirements (ICRs)

The following proposed changes will be submitted to OMB for review under OMB control number 0938–1218 (CMS–10510).

(1) ICRs Regarding the BHP Blueprint (§ 600.125)

We propose at § 600.125(a)(1)–(3) that Blueprint revisions must be submitted to reflect: (1) changes in Federal laws, regulations, policy interpretations or court decisions that affect provisions in the certified Blueprint; (2) significant changes that alter core program operations or the BHP benefit package; or (3) changes to enrollment, disenrollment, and verification policies described in the certified Blueprint. We note that only § 600.125(a)(1) is a new requirement. The requirements under § 600.125(a)(2) and (3) are existing. We propose at § 600.125(b) that a State may submit revisions to its certified Blueprint at any time within the same quarter of the proposed effective date of revised Blueprint. We propose at § 600.125(c) that HHS must review the revised Blueprint within 90 calendar days or provide the State written notice of disapproval or additional information it needs to make a final determination.

We estimate that, on average, a State operating a BHP will submit one revised Blueprint in response to § 600.125(a)(1) annually. Because only two States are currently certified to operate a BHP, we are providing the burden estimate for two States. We estimate that the proposal under § 600.125(a)(1) will increase State burden. We estimate that the proposals under § 600.125(b) and (c) will have no impact on State burden. We estimate that, on average, it will take a State 4 additional hours at $80.08/hr for a Business Operations Specialist and 2 additional hours at $118.14/hr for a General Manager to meet the new Blueprint requirements under § 600.125(a)(1). In aggregate, we estimate an increased burden of 12 hours (2 States × 6 hr/State) at a cost of $1,113 [2 States × ((4 hr × $80.08/hr) + (2 hr × $118.14/hr))]. We note that this cost will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

(2) ICRs Regarding the Operation of a BHP (§§ 600.145(a), 600.145(f)(2), and 600.330(f))

We propose at § 600.145(a) that a State must implement its BHP in accordance with: (1) the approved and full certified State BHP Blueprint; or (2) the approved suspension application (see ICR section 3 below).

We propose at § 600.145(f)(2) that the State operating a BHP must perform eligibility and health services appeals as specified in § 600.335.

The ongoing burden associated with the requirements under § 600.145 is the time and effort it would take each participating State to perform the recordkeeping and reporting portions of the core operating functions of a BHP including eligibility determinations and appeals as well as enrollment and disenrollment, health plan contracting, oversight and financial integrity, consumer assistance, and if necessary program termination or suspension.

Because only two States are currently certified to operate a BHP, we are providing the burden estimate for two States. We estimate that it would take a business operations specialist 4 additional hours at $80.08/hr to meet these new recordkeeping and reporting requirements for health services appeals. In aggregate, we estimate an increased burden of 8 hours (2 States × 4 hr/response) at a cost of $641 (2 States × 4 hr × $80.08/hr). We note that this cost will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

We propose at § 600.330(f), BHP eligibility notices must be written in plain language and be provided in a manner which ensures individuals with disabilities are provided with effective communication and takes steps to provide meaningful access to eligible individuals with limited English proficiency. These notices must be developed and processed in a coordinated fashion with other insurance affordability programs which have the same accessibility standards at 45 CFR 155.230(b). As such, we propose no additional burden for the BHP for the noticing requirement.

(3) ICRs Regarding Suspension of a BHP (§§ 600.140(b) and 600.170(a)(2))

We propose at § 600.140(b)(1) if a State decides to suspend its BHP or requests a suspension extension, a State must submit to the Secretary a suspension application or suspension extension application. We propose at § 600.140(b)(3) that a State must submit written notices to all BHP enrollees and participating standard health plan offers at least 90 days prior to the effective date of the suspension. We propose at § 600.140(b)(4) that the State must submit to HHS within 12 months of the suspension effective date the data required by § 600.610 needed to complete the financial reconciliation process with HHS. We propose at § 600.140(b)(5) that the State must submit the annual report required by § 600.170(a)(2). We propose at § 600.140(b)(6) that the State must annually remit to HHS any interest that has accrued on the balance of the BHP trust fund during the suspension period. We propose at § 600.140(b)(7) that the State must submit a transition plan to HHS that describes how the State will reinstate its BHP or terminate the program.

Two States are currently certified to operate a BHP; therefore, we are providing the burden estimate for two States.

We estimate that, on average, it would take a Business Operations Specialist 30 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to submit a suspension application to the Secretary. In aggregate, we estimate a one-time burden of 68 hours (2 States × 34 hr/response) at a cost of $5,780 [2 States × ((30 hr × $80.08/hr) + (4 hr × $118.14/hr))]. We estimate that, on average, it would take a Business Operations Specialist 30 hours at $80.08/hr and a General Manager 4

hours at $118.14/hr to submit a suspension extension application to the Secretary. In aggregate, we estimate a one-time burden of 68 hours (2 States × 34 hr/response) at a cost of $5,780 [2 States × ((30 hr × $80.08/hr) + (4 hr × $118.14/hr))].

We estimate that, on average, it would take a Business Operations Specialist 32 hours at $80.08/hr to prepare and submit notification to all participating standard health plans and enrollees. In aggregate, we estimate a one-time burden of 64 hours (2 States × 32 hr/response) at a cost of $5,125 [2 States × (32 hr × $80.08/hr)].

We estimate that it would take a Business Operations Specialist 25 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to compile and submit data required for quarterly financial reconciliation. In aggregate, we estimate an annual burden of 232 hours (2 States × 29 hr/response × 4 responses/yr) at a cost of $19,796 [2 States × 4 responses/yr ((25 hr × $80.08/hr) + (4 hr × $118.14/hr)).

We estimate that, on average, it would take a Financial Specialist 8 hours at $88.74/hr to remit annually the interest accrued on the balance of the BHP trust fund while in suspension. In aggregate, we estimate an annual burden of 16 hours (2 States × 8 hr/response) at a cost of $1,420 [2 States × (8 hr × $88.74/hr)].

We estimate that it would take a Business Operations Specialist 20 hours at $80.08/hr and a General Manager 4 hours at $118.14/hr to submit a transition plan to reinstate its BHP or terminate the program. In aggregate, we estimate a one-time burden of 48 hours (2 States × 24 hr/response) at a cost of $4,148 [2 States × ((20 hr × $80.08/hr) + (4 hr × $118.14/hr))].

We estimate that, on average, it will take a Business Operations Specialist 40 hours at $80.08/hr and 4 hours at $118.14/hr for a General Manager to complete and submit the State's annual report, for a total annual burden of 88 hours at a cost of $7,352 [2 States × ((40 hr × $80.08/hr) + (4 hr × $118.14/hr))]. We note that these costs will be incurred 100 percent by the State, as Federal BHP funds cannot be used for program administration.

b. Burden Summary

TABLE 58: Summary of Proposed Burden Estimates

Regulation Section(s)/ ICR Provision	OMB Control No./ CMS-ID	Year	Number of Respondents	Number of Responses	Time per Response (hrs)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
600.125(a)(1)	0938–1218 (CMS-10510)	2024	2	2	6	12	Varies	1,113	1,113	N/A
600.145(a) and 600.145(f)(2)	0938–1218 (CMS-10510)	2024	2	2	4	8	80.08	641	641	N/A
600.140(b)(1) (suspension application)	0938–1218 (CMS-10510)	2024	2	2	34	68	Varies	5,780	5,780	N/A
600.140(b)(1) (extension application	0938–1218 (CMS-10510)	2024	2	2	34	68	Varies	5,780	5,780	N/A
600.140(b)(3)	0938–1218 (CMS-10510)	2024	2	2	32	64	80.08	5,125	5,125	N/A
600.140(b)(4)	0938–1218 (CMS-10510)	2024	2	4	29	232	Varies	19,796	19,796	N/A
600.140(b)(5) and 600.170(a)(2)	0938–1218 (CMS-10510)	2024	2	2	44	88	Varies	7,352	7,352	N/A
600.140(b)(6)	0938–1218 (CMS-10510)	2024	2	2	8	16	88.74	1,420	1,420	N/A
600.140(b)(7)	0938–1218 (CMS-10510)	2024	2	2	24	48	Varies	4,148	4,148	N/A
Total					Varies		Varies	51,155	51,155	

11. The Quality Payment Program (QPP) (42 CFR Part 414 and Section IV. of This Proposed Rule)

The following QPP-specific ICRs reflect changes to our currently approved burden due to proposed policy changes in this CY 2024 proposed rule as well as adjustments to the policies that have been previously finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, and 87 FR 70131, respectively) due to revised assumptions based on updated data available at the time of the publication of this proposed rule.

a. Background

(1) ICRs Associated With Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)

In the following sections, we discuss a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The following sections describe the changes in the estimated burden for the information collections relevant to the proposed revisions in the policies associated with the CY 2024 PFS proposed rule and the proposed revisions to our currently approved information requests for MIPS and Advanced APM ICRs. The proposed estimated burden will be submitted to OMB under control number 0938–1314 (CMS–10621). The proposed estimated burden for the CAHPS for MIPS Survey discussed in sections V.B.11.c.(5), V.B.11.e.(8), and V.B.11.e.(9) of this rule will be submitted under OMB control number 0938–1222 (CMS–10450). We note that we have received approvals for the collection of information associated the virtual group election process under OMB control number 0938–1343 (CMS–10652).

(2) Summary of Proposed Changes for the Quality Payment Program: MIPS

We have included the change in the estimated burden for the CY 2024 performance period/2026 MIPS payment year due to the proposed policies and information collections in this proposed rule. The proposed policies in this proposed rule impact the burden estimates for the CY 2024 performance period/2026 MIPS payment year.

The following five MIPS ICRs show changes in burden due to the proposed policies in this proposed rule: (1) Quality performance category data submission by Medicare Part B claims collection type; (2) Quality performance category data submission by qualified clinical data registry (QCDR) and MIPS CQM collection type; (3) Quality performance category data submission by eCQM collection type; (4) MIPS Value Pathways (MVP) quality performance category submission, and (5) MVP registration. In aggregate, we estimate the proposed policies will result in a net decrease in burden of 4,002 hours and $459,553 for the CY 2024 performance period/2026 MIPS payment year. The remaining changes to our currently approved burden estimates are proposed adjustments due to the revised burden assumptions based on the updated data available at the time of publication of this proposed rule. As discussed in section VII.E.23.a. of this proposed rule, we are basing our estimates on data from the CY 2021 performance period.

We are proposing to add two new ICRs, ''QCDR full self-nomination process'' and ''qualified registry full self-nomination process'' in sections V.B.11.c.(2) and V.B.11.c.(3) of this rule to distinctly capture the burden for the number of QCDRs and qualified registries submitting applications for the simplified and full self-nomination process. We note that the proposed addition of these ICRs is not due to the proposed policy changes in section IV.A.4.k. of this rule. It is a proposed change in our approach in representing the estimated burden for the third -party intermediary self-nomination process due to availability of updated data.

We are proposing to remove one ICR, ''nomination of Promoting Interoperability measures,'' in section V.B.11.h. of this rule. We note that the proposed removal of the ICR is not due to proposed policy changes in section IV.A.4.f.(4) of this rule. It is due to a consistent decline in the number of submissions received for the ICR.

We are not proposing any changes or adjustments to the following ICRs: Registration for virtual groups; OAuth credentialing and token request process; Quality Payment Program identity management application process; subgroups registration; submitting Promoting Interoperability data; improvement activities submission; nomination of MVPs; and opt-out of performance data display on Compare Tools for voluntary participants. See section V.B.11. of this proposed rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted by two primary factors. First, we are unable to predict with absolute certainty who will be a Qualifying APM Participant (QP) for the CY 2024 performance period/ 2026 MIPS payment year. New eligible clinician participants in Advanced APMs who become QPs will be excluded from MIPS reporting requirements and payment adjustments, and as such, are unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians may not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2024 performance period/2026 MIPS payment year compared to the CY 2021 performance period/2023 MIPS payment year. Therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data. Additionally, we will continue to update our estimates annually as data becomes available.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), we did not implement any changes to currently approved burden estimates for the CY 2024 performance period/2026 MIPS payment year. Therefore, we did not propose any changes to the Partial QP elections; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of Data for QP determinations under the All-Payer Combination Option.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 59 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. In Table 59, MIPS eligible clinicians and other clinicians voluntarily submitting

data to MIPS may submit data as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted. Beginning with the CY 2023 performance period/2025 MIPS payment year, clinicians could also participate as subgroups for reporting measures and activities in an MVP. We note that the subgroup reporting option is not available for clinicians participating in traditional MIPS. We finalized in the CY 2022 PFS final rule that a subgroup reporting measures and activities in an MVP will submit its affiliated group's data for the Promoting Interoperability performance category and in the scenario that a subgroup does not submit its affiliated group's data, the subgroup will receive a zero score for the Promoting Interoperability performance category (86 FR 65413 through 65414).

Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 59.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. We previously finalized in the CY 2021 PFS final rule that the APM Performance Pathway is available for both Accountable Care Organization (ACO) participants and non-ACO participants to submit quality data (85 FR 84859 through 84866). Due to data limitations and our inability to determine who will use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2024 performance period/2026 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. We also want to note that as finalized in the CY 2022 PFS final rule (86 FR 65259 through 65263), the CMS Web Interface collection type is available through the CY 2024 performance period/2026 MIPS payment year only for clinicians participating in the Shared Savings Program. Per section 1899(c) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. Additionally, we finalized the introduction of a voluntary reporting option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level beginning with the CY 2023 performance period/2025 MIPS payment year (87 FR 70087 and 70088). For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we established that, for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the improvement activities inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM Entity receives less than the maximum improvement activities performance category score, to date all MIPS APM Entities have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844).

TABLE 59: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician

Type of Data Submitted	Category of Clinician
Quality Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Subgroup reporting is only available for clinicians participating in MVP reporting.
Promoting Interoperability Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. Each eligible clinician in an APM Entity could report data for the Promoting Interoperability performance category at the individual level, or as part of their group TIN, or under their APM Entity TIN. The burden estimates for this proposed rule assume group TIN-level reporting.
Improvement Activities Performance Category	Individual clinician (MIPS eligible, voluntary, opt-in), group, virtual group, subgroup, or APM Entity. The burden estimates for this proposed rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.
Reweighting Applications for extreme and uncontrollable circumstances and significant hardship or other exceptions	Clinicians who submit an application may be eligible for a reweighting of the approved performance category to zero percent under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances and significant hardship or another type of exception. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category as described in § 414.1380(c)(2)(i)(A)(4).
MVP and Subgroup Registration	An MVP participant, as described at § 414.1305, electing to submit data for the measures and activities in an MVP must register. Clinicians who choose to participate as a subgroup for reporting an MVP must also register.
Partial QP Election	Eligible clinicians who attain Partial QP status and choose to participate in MIPS would need to submit a partial QP election form.
Registration for the CAHPS for MIPS Survey	Groups electing to use a CMS-approved survey vendor to administer the CAHPS for MIPS survey must register.
Virtual Group Registration	Virtual groups must register via email. Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.
APM Performance Pathway	Clinicians in MIPS APMs electing the APM Performance Pathway. The burden estimates for this proposed rule assume that ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option (available through the CY 2024 performance period/2026 MIPS payment year), and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an APM Entity.

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59452, 84 FR 62568, 85 FR 84472, 86 FR 64996, and 87 FR 70131), and continued in this proposed rule create some additional data collection requirements not listed in Table 59. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–

10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs related to MIPS third-party intermediaries (see section V.B.11.c. of this proposed rule):

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314)
- Third party intermediary plan audits
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (OMB 0938–1314) (85 FR 84969 through 84970).

Additional ICRs related to the data submission and the quality performance category (see section V.B.11.e. of this proposed rule):

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs related to the Promoting Interoperability performance category (see section V.B.11.g. of this proposed rule):

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs related to call for new MIPS measures and activities (see sections V.B.11.j, V.B.11.f, V.B.11.k., and V.B.11.h. of this proposed rule):

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (85 FR 84990 through 84991) (OMB 0938–1314)

Additional ICRs related to MIPS (see section V.B.11.o. of this proposed rule):

- Opt out of performance data display on Compare Tools for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs related to APMs (see sections V.B.11.m. and V.B.11.n. of this proposed rule):

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule does not propose any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not proposing any changes under that control number.

c. ICRs Regarding Third Party Intermediaries (§ 414.1400)

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621). As discussed above in section V.B.11.a.(2) of this rule, we are proposing to add two new ICRs, ''QCDR simplified self-nomination process'' and ''qualified registry self-nomination process'', to represent the estimated burden for the third-party intermediaries submitting applications for the simplified self-nomination process. We discuss the details of these proposed changes in the below sections.

In section IV.A.4.k. of this rule, we are proposing to: (1) add requirements for third party intermediaries to obtain documentation; (2) add requirements for third party intermediaries to submit data in the form and manner specified by CMS; (3) specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (4) add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (5) add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (6) modify requirements for QCDRs and qualified registries to support MVP reporting; (7) specify requirements for a transition plan for QCDRs and qualified registries; (8) specify requirements for data validation execution reports; (9) eliminate the Health IT vendor category; (10) add failure to maintain updated contact information as criteria for remedial action; (11) revise corrective action plan requirements; (12) specify the process for publicly posting remedial action; and (13) specify the criteria for audits. Specifically, we note that the proposed policy to eliminate the health IT vendor category beginning with the CY 2025 performance period/2027 MIPS payment year, if finalized, would not have any impact on the estimated burden for third party self-nomination process in the CY 2024 performance period/2026 MIPS payment year. If the proposed removal of health IT vendor category is finalized for the CY 2025 performance period/2027 MIPS payment year, we recognize that it could encourage some existing health IT vendors to complete the requirements under the qualified registry self-nomination process. However, we believe that many third-party intermediaries serve as both health IT vendors and qualified registries for the purposes of submitting data for MIPS eligible clinicians. Therefore, we assume that there would not be an increase in the number of qualified registries that would submit applications for the qualified registry self-nomination process during the CY 2024 performance period/2026 MIPS payment year.

We assume that the proposed changes to codify previously finalized preamble language related to third party intermediaries in the regulatory text would result in modifying the regulatory text to reflect previously finalized policies for third party intermediaries or provide additional clarification of the previously finalized policies. We do not expect to receive additional information from QCDRs and qualified registries during the self-nomination process due to the above proposed policies and therefore, we are not proposing any adjustments to the currently approved burden estimates for third party intermediaries. We refer readers to section IV.A.4.k. of this rule for details on proposed policies for third party intermediaries. Additionally, we refer readers to section VII.E.23.e.(2)(a) of this proposed rule where we discuss the details in our impact analysis for these policies.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure,

or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nomination process annually.[333] The processes for self-nomination of entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

As described below in section V.B.11.c.(2)(a) of this rule, we are proposing to separate the burden for the number of QCDR self-nomination applications submitted for the simplified and full self-nomination process for the CY 2024 performance period/2026 MIPS payment year. In the CY 2023 PFS final rule (87 FR 70137 through 70139), we used the same estimate for the number of respondents that submitted applications for the simplified and full self-nomination process because we did not have separate estimates at the time. Additionally, we only used the burden for the full QCDR self-nomination process in our final burden summary estimates. Due to the availability of updated data and the distinct number of estimated respondents for the simplified and full self-nomination process, we are proposing to add a new ICR to capture the burden for the simplified QCDR self-nomination process. We note that the proposed change in estimated burden is not due to policy proposals in section IV.A.4.k. of this rule. In order to accurately represent the estimated burden incurred by the QCDRs for the simplified and full self-nomination process, we discuss the burden under separate ICRs. We are not proposing any changes to our estimates for the number of existing or borrowed QCDR measures submitted for consideration by each QCDR at the time of self-nomination and the average time required to submit information for each QCDR measure.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77507 through 77508, and 82 FR 53906 through 53908, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 59998 through 60000, 84 FR 63116 through 63121, 85 FR 84964 through 84969, 86 FR 65569 through 65573, and 87 FR 70138 through 70139, respectively) for our previously finalized requirements and estimated burden for self-nomination of QCDRs and nomination of QCDR measures.

(a) Self-Nomination Process and Other Requirements

Based on the number of applications that we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 45 QCDRs would submit applications using the simplified self-nomination process. We note that we are not making any changes to the currently approved time of 8.1 hours required for the simplified QCDR self-nomination process (87 FR 70139).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

As shown in Table 60, we assume that the staff involved in the simplified QCDR self-nomination process will continue to be computer systems analysts or their equivalent who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response would be $837.54 (8.1hr × $103.40/hr). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the simplified QCDR self-nomination process would be 365 hours (45 responses × 8.1 hr) at a cost of $37,689 (45 applications × $837.54/application).

TABLE 60: Estimated Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Simplified QCDR Self-Nomination Applications submitted (a)	45
Annual Hours Per QCDR for Simplified Process (b)	8.1
Total Annual Hours for Self-nomination (c) = (a) * (b)	**365**
Cost per Application at Labor Cost for computer systems analysts at $103.40/hr (d)	$837.54
Total Annual Cost (**e**) = (a) * (d)	**$37,689**

In Table 61, the addition of this new ICR for the CY 2024 performance period/2026 MIPS payment year would result in an increase of 365 hours at a cost of $37,689 for the simplified QCDR self-nomination process. We note that the proposed increase in burden is due to separating the estimated burden for the simplified QCDR self-nomination process.

[333] As stated in the CY 2019 PFS final rule (83 FR 59998), health IT vendors are not included in the burden estimates for MIPS.

TABLE 61: Change in Estimated Burden for Simplified QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	0
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 60, row (c))	365
Difference (c) = (b) - (a)	**+365**
Total Currently Approved Annual Cost (d)	0
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 60, row (e))	$37,689
Difference (f) = (e) - (d)	**+$37,689**

(b) Full QCDR Self-Nomination Process and Other Requirements

Based on the number of applications that we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 10 QCDRs would submit applications using the full self-nomination process. This is a decrease of 53 respondents from the currently approved estimate of 63 for the QCDR self-nomination process (87 FR 70139). We note that we are not making any changes to the currently approved time of 10.1 hours required for the full QCDR self-nomination process (87 FR 70139).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

In Table 62, we assume that the staff involved in the full QCDR self-nomination process will continue to be computer systems analysts or their equivalent who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response would be $1,044.34 (10.1hr × $103.40/hr). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the full QCDR self-nomination process would be 101 hours (10 responses × 10.1 hr) at a cost of $10,443 (10 applications × $1,044.34/application).

TABLE 62: Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
# of Full QCDR Self-Nomination Applications submitted (a)	10
Annual Hours Per QCDR for Full Process (b)	10.1
Total Annual Hours for Full Self-nomination (c) = (a) * (b)	**101**
Cost per Application at Labor Cost computer systems analyst at $103.40/hr (d)	$1,044.34
Total Annual Cost (**e**) = (a) * (d)	**$10,443**

In Table 63, we use the currently approved burden as the baseline for calculating the net change in burden for the full QCDR self-nomination process. We note that we discussed the estimated burden for the full QCDR self-nomination process under ''maximum burden'' in Table 105 in the CY 2023 PFS final rule (87 FR 70139). For the CY 2024 performance period/2026 MIPS payment year, the change in the representation of burden for this ICR described above results in a decrease of 535 hours and $55,350 for the full self-nomination process. We also note that the decrease in burden accounts for the change due to separating the estimated burden based on the simplified and full self-nomination process.

TABLE 63: Change in Estimated Burden for Full QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	636
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 62, row (c))	101
Difference (c) = (b) - (a)	**-535**
Total Currently Approved Annual Cost (d)	$65,793
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 62, row (e))	$10,443
Difference (f) = (e) - (d)	**-$55,350**

(c) QCDR Measure Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77375 through 77377), we established that QCDRs could submit measures that are not on the annual list of MIPS quality measures as part of the self-nomination process for an entity to become a QCDR.

In section IV. of this rule, we are proposing to add that if the measure was submitted for consideration after self-nomination to our list of reasons for rejecting a QCDR measure at § 414.1400(b)(4)(iv)(O). We will not revise or adjust our active requirements or burden estimates because the proposed policy only clarifies requirements for rejecting a QCDR measure and will not substantively change the currently approved estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

In section IV. of this rule, we are proposing at § 414.1400(b)(4)(iv)(P) that a QCDR measure may be rejected if the QCDR submits more than 30 quality measures not in the annual list of MIPS quality measures for CMS consideration. We will not revise or adjust our currently approved burden estimates as result of this change because limiting the number of measures submitted during the QCDR self-nomination process would not substantively change the currently approved estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

In section IV.A.4.k.(4)(b)(i) of this rule, we are proposing to revise § 414.1400(b)(4)(i)(B) to add a provision that the approved QCDR measure specifications must remain published through the performance period and data submission period. We will not revise or adjust our currently approved burden estimates as result of this change because establishing a standard for the duration of posting the approved QCDR measure specifications would not substantively change the currently approved estimated average weighted time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

(3) Qualified Registry Self-Nomination Process and Other Requirements

We refer readers to § 414.1400(b)(2) which states that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so.

As described below, in this rule we are proposing to separate the burden for the number of qualified registry self-nomination applications submitted for the simplified and full self-nomination process for the CY 2024 performance period/2026 MIPS payment year. In the CY 2023 PFS final rule (87 FR 70139 through 70140), we used the same estimate for the number of respondents that submitted applications for the simplified and full self-nomination process because we did not have separate estimates at the time. Additionally, we only used the burden for the full qualified registry self-nomination process in our final burden summary estimates. Due to the availability of updated data and the distinct number of estimated respondents for the simplified and full self-nomination process, we are proposing to add a new ICR to capture the burden for the qualified registry self-nomination process. We note that the proposed change is not due to policy proposals in section IV.A.4.k. of this rule. With the addition of a new ICR, we believe that we would be able to accurately represent the estimated burden incurred by the qualified registries for both the simplified and full self-nomination process.

(a) Simplified Qualified Registry Self-Nomination Process

Based on the number of applications that we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate that 89 qualified registries would submit applications using the simplified self-nomination process. We note that we are not making any changes to the currently approved time of 0.5 hours required for the simplified qualified registry self-nomination process (87 FR 70140).

Based on the above assumptions, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit data on behalf of MIPS eligible clinicians.

In Table 64, we assume that the staff involved in the simplified qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average adjusted labor rate of $103.40/hr. We estimate the burden per response would be $51.70 (0.5hr × $103.40/hr) for the simplified self-nomination process. In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the simplified qualified registry self-nomination process would be 45 hours (89 responses × 0.5 hr) at a cost of $4,601 (89 applications × $51.70//application).

TABLE 64: Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Simplified Self-Nomination Applications submitted (a)	89
Annual Hours Per Qualified Registry for Simplified Process (b)	0.5
Total Annual Hours for Simplified Self-nomination (c) = (a) * (b)	**45**
Cost per Application at Labor Cost computer systems analyst at $103.40/hr (d)	$51.70
Total Annual Cost (**e**) = (a) * (d)	**$4,601**

In Table 65, the addition of this ICR for the CY 2024 performance period/2026 MIPS payment year would result in a change of +45 hours at a cost of $4,601 for the simplified qualified registry self-nomination process. We note the increase in burden is due to separating the estimated burden for the simplified and full qualified registry self-nomination process.

TABLE 65: Change in Estimated Burden for Simplified Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	0
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 64, row (c))	45
Difference (c) = (b) - (a)	**+45**
Total Currently Approved Annual Cost (d)	$0
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 64, row (e))	$4,653
Difference (f) = (e) - (d)	**+$4,653**

(b) Full Qualified Registry Self-Nomination Process

Based on the number of applications we expect to receive during the CY 2023 self-nomination period for the CY 2024 performance period/2026 MIPS payment year, we estimate 36 qualified registries would submit applications using the full self-nomination process. This is a decrease of 96 from the currently approved estimate of 132 for the qualified registry self-nomination process (87 FR 70140). We note we are not making any changes to our currently approved per response time estimate of 0.5 hours for the simplified qualified registry self-nomination process and 2 hours for the full qualified registry self-nomination process (87 FR 70139 through 70140).

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit data on MIPS eligible clinicians.

In Table 66, we assume the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. We estimate the burden per response would be $206.80 (2 × 103.40/hr) for the full self-nomination process. In aggregate, for the CY 2024 performance period/2026 MIPS payment year, we estimate that the annual burden for the full qualified registry self-nomination process would be 72 hours (36 responses × 2 hr) at a cost of $7,445 (36 applications × $206.80/application).

TABLE 66: Estimated Burden for Qualified Registry Full Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
# of Qualified Registry Full Self-Nomination Applications submitted (a)	36
Annual Hours Per Qualified Registry for Full Process (b)	2
Total Annual Hours for Full Self-Nomination (c) = (a) * (b)	**72**
Cost per Application at Labor Cost (computer systems analyst's labor rate of $103.40/hr) (d)	$206.80
Total Annual Cost (e) = (a) * (d)	**$7,445**

In Table 67, we use the currently approved burden as the baseline for calculating the net change in burden for the simplified qualified registry self-nomination process. We note that we discussed the estimated burden for the

full qualified registry self-nomination process under ''maximum burden'' in Table 107 in the CY 2023 PFS final rule (87 FR 70140). For the CY 2024 performance period/2026 MIPS payment year, the change in the representation of burden for this ICR described above results in a decrease of 192 hours and a decrease of $19,853 for the full qualified registry self-nomination process. We note the decrease in burden accounts for the changes due to separating the estimated burden based on the simplified and full qualified registry self-nomination process.

TABLE 67: Change in Estimated Burden for Full Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Time (hr) (a)	264
Total Annual Time (hr) for Respondents in CY 2024 PFS proposed rule (b) (See Table 66, row (c))	72
Difference (c) = (b) - (a)	**-192**
Total Currently Approved Annual Cost (d)	$27,298
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 66, row (e))	$7,445
Difference (f) = (e) - (d)	**-$19,853**

(4) Third Party Intermediary Plan Audits

The following proposed changes associated with developing the plans and audits by QCDRs and qualified registries will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

(a) Targeted Audits

In the CY 2022 PFS final rule (86 FR 65547 through 65548), we finalized that beginning with the CY 2021 performance period/CY 2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with requirements at § 414.1400(b)(3)(vi). Consistent with our assumptions in the CY 2022 PFS and CY 2023 PFS final rules for the QCDRs (86 FR 65574 and 87 FR 70141 respectively) and qualified registries (86 FR 65571 and 87 FR 70141 respectively) that would submit the results of targeted audits, we estimate the time required for a QCDR or qualified registry to submit a targeted audit ranges between 5 and 10 hours for the simplified and full self-nomination process, respectively. We assume the staff involved in submitting the targeted audits will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr.

Based on the number of data validation execution reports submitted for the CY 2021 performance period/2023 MIPS payment year, we estimate that 33 third party intermediaries (13 QCDRs and 20 qualified registries) will submit targeted audits for the CY 2024 performance period/2026 MIPS payment year (See Table 68). We estimate that the cost for a QCDR or a qualified registry to submit a targeted audit will range from $517 (5 hr × $103.40/hr) to $1,034 (10 hr × $103.40/hr). In aggregate, we estimate an annual burden ranging from 165 hours (33 responses × 5 hr/audit) and $17,061 (33 targeted audits × $517/audit) to 330 hours (33 responses × 10 hr/audit) and $34,122 (33 targeted audits × $1,034/audit) (see Table 69 for the cost per audit).

(b) Participation Plans

In the CY 2022 PFS final rule (86 FR 65546), we finalized requirements for approved QCDRs and qualified registries that did not submit performance data and therefore will need to submit a participation plan as part of their self-nomination process. We refer readers to § 414.1400(e) for additional details on policies for remedial action and termination of third-party intermediaries.

Consistent with our assumptions in the CY 2023 PFS final rule for the QCDRs and qualified registries (87 FR 70141) that will submit participation plans, we estimate that it will take 3 hours for a QCDR or qualified registry to submit a participation plan during the self-nomination process. We assume the staff involved in submitting a participation plan will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr.

As shown in Table 68, we are not changing our currently approved estimate that 75 third party intermediaries [five self-nomination participation plans (two QCDRs and three qualified registries) and 70 QCDR measure participation plans] will submit participation plans for the CY 2024 performance period/2026 MIPS payment year.

In Table 69, we estimate that the cost for a QCDR or a qualified registry to submit a participation plan is $310.20 (3 hours × $103.40/hr). In aggregate, we estimate the total impact associated with QCDRs and qualified registries to submit participation plans would be 225 hours (75 participation plans × 3 hr/plan) at a cost of $23,265 (75 participation plans × $310.20/plan) (see Table 69 for the cost per audit).

(c) Corrective Action Plans (CAPs)

In the CY 2017 Quality Payment Program final rule, we established the process for corrective action plans (CAPs) (81 FR 77386 through 77389). In section IV.A.4.k.(6)(b), we are proposing an additional provision at § 414.1400(e)(2)(iv) to allow us to immediately or with advance notice terminate a third party intermediary that has not maintained current contact information for correspondence. Additionally, we propose to add at § 414.1400(e)(2)(v) that we may terminate third party intermediaries that are on remedial action for two consecutive years. We are not proposing any changes to our currently approved estimated burden due to these proposals because these changes provide additional rationale for remedial action policies and do not add any additional requirements for third party intermediaries.

Based on the increased number of QCDR and qualified registries that required remedial actions for the CY 2022 performance period/2024 MIPS payment year, we anticipate the same

trend would continue for the CY 2024 performance period/2026 MIPS payment year. Therefore, we estimate 17 third party intermediaries will submit CAPs for the CY 2024 performance period/2026 MIPS payment year. This is an increase of seven respondents from the currently approved estimate of ten (87 FR 70142). We are not changing our currently approved estimate of 3 hours for a QCDR or qualified registry to submit a CAP. We also assume the staff involved in submitting the CAP will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. As shown in Table 69, we estimate that the cost for a QCDR or a qualified registry to submit a CAP is $310.20 (3 hours × $103.40/hr). In aggregate, we estimate the total impact associated with QCDRs and qualified registries to CAPs will be 51 hours (17 CAPs × 3 hr/plan) at a cost of $5,273 (17 CAPs × $310.20/plan).

(d) Transition Plans

In the CY 2020 PFS final rule (84 FR 63052 through 63053), we established a policy at § 414.1400(a)(4)(vi) which states a condition of approval for the third party intermediary is to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan. In this rule, we estimate we will receive five transition plans for the CY 2024 performance period/2026 MIPS payment year. This adjustment would result in a decrease of five from the currently approved estimate of 10 (87 FR 70142). We continue to estimate it will take approximately 1 hour for a computer system analyst or their equivalent at a labor rate of $103.40/hr to develop a transition plan on behalf of each QCDR or qualified registry during the self-nomination period. However, we are unable to estimate the burden for implementing the actions in the transition plan because the level of effort may vary for each QCDR or qualified registry. In aggregate, we estimate the impact associated with qualified registries completing transition plans is 5 hours (5 transition plans × 1 hr/plan) at a cost of $517 (5 hr × $103.40/hr). We refer readers to section VII.E.23.e.(2)(a) of this proposed rule where we discuss our impact analysis for the transition plans submitted by QCDRs and qualified registries.

In section IV.A.4.k.(6)(c) of this rule, we are proposing at § 414.1400(e)(1)(i)(F) an additional requirement for the QCDR or qualified registry under a corrective action plan to communicate the final resolution to CMS once the resolution is complete and to provide an update, if any, to the monitoring plan provided under § 414.1400(e)(1)(i)(C). We believe the proposed revision would ensure third party intermediaries complete the requirements within the communication plan and would not add any additional requirements for a third-party intermediary to submit a CAP.

In section IV.A.4.k.(6)(d) of this rule, we are proposing to add a new provision at § 414.1400(e)(1)(ii)(B) that we may publicly disclose on the CMS website that CMS took remedial action on the third party intermediary or terminated it. We are also proposing to modify § 414.1400(e)(1)(ii) by redesignating it as § 414.1400(a)(2)(ii)(A) and ending the policy after the CY 2025 MIPS reporting period/CY 2027 MIPS payment year.

In section IV.A.4.k.(6)(e) of this rule, we are proposing to modify § 414.1400(a)(2)(ii)(A) to state that our consideration can include past compliance including remedial actions. We are proposing at § 414.1400(f) that third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. We are also proposing to redesignate the existing section § 414.1400(f) (which includes paragraphs (f)(1), (2), and (3)) as paragraph (a)(3)(vii) with no changes in the text.

We do not expect to receive additional information from QCDRs and qualified registries during the self-nomination process due to the above proposed policies and therefore, are not proposing any adjustments to the currently approved burden estimates for third party intermediary plan audits. Additionally, we refer readers to section VII.E.23.e.(2)(a) of this proposed rule where we discuss the details in our impact analysis for these policies.

(e) Final Burden for Third Party Intermediary Plan Audits

In aggregate, as shown in Table 68, we assume that 130 third party intermediaries will submit plan audits (33 targeted audits, 75 participation plans, 17 CAPs, and 5 transition plans).

TABLE 68: Estimated Number of Respondents to Submit Plan Audits

Burden and Respondent Descriptions	# of Respondents
# of Targeted Audits (a)	33
# of Participation Plans (b)	75
# of Corrective Action Plans (CAPs) (c)	17
# of Transition Plans (d)	5
Total Respondents (e) = (a) + (b) + (c) + (d)	**130**

In Table 69, we assume that the staff involved in the submission of the plan audits during the third party intermediary self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $103.40/hr. For the CY 2024 performance period/2026 MIPS payment year, in aggregate, the proposed estimated annual burden for the submission of third party intermediary plan audits will range from 446 hours to 611 hours at a cost ranging from $46,116 (446 hr × $103.40/hr) and $63,177 (611 hr × $103.40/hr) (see Table 69).

TABLE 69: Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
# of Hours per Completion of Targeted Audit (a)	5	10
Total Annual Hours for Completion of 33 Targeted Audits (b)	**165**	**330**
# of Hours per Submission of Participation Plan (c)	3	3
Total Annual Hours for Submission of 75 Participation Plans (d)	**225**	**225**
# of Hours per Submission of CAP (e)	3	3
Total Annual Hours for Submission of 17 CAPs (f)	**51**	**51**
# of Hours per Submission of Transition Plan (g)	1	1
Total Annual Hours for Submission of 5 Transition Plans (h)	**5**	**5**
Total Annual Hours for Submission of Plan Audits (i) = (b) + (d) + (f) + (h)	**446**	**611**
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $103.40/hr) (j) = (a) * $103.40/hr	$517	$1,034
Cost Per Participation Plan (@ computer systems analyst's labor rate of $103.40/hr) (k) = (c) * $103.40/hr	$310.20	$310.20
Cost per CAP (@ computer systems analyst's labor rate of $103.40/hr) (l) = (e) * $103.40/hr	$310.20	$310.20
Cost per Transition Plan @computer systems analyst's labor rate of $103.40/hr (m) = (g) * $103.40/hr	$103.40	$103.40
Total Annual Cost (n) = 33 * (j) + 75 * (k) + 17 * (l) + 5 * (m) (simplified) and 33 * (j) + 75 * (k) + 17 * (l) + 5 * (m) (full)	**$46,116**	**$63,177**

In Table 70, for the CY 2024 performance period/2026 MIPS payment year, the change in the number of respondents for third party intermediary plan audits results in a change of +21 hours at a cost of +$2,171 for the simplified self-nomination process and +26 hours at a cost of +$2,688 for the full self-nomination process.

We note for the purposes of calculating proposed estimated change in burden in Tables 96 through 98 of this rule, we use only estimated burden for the plan audits submitted under the full self-nomination process.

TABLE 70: Change in Estimated Burden for Third Party Intermediary Plan Audits

Burden and Respondent Descriptions	Simplified Process	Full Process
Total Currently Approved Annual Hours (a)	425	585
Total Annual Hours for Respondents in CY 2023 PFS final rule (b) (See Table 69, row (i))	446	611
Difference (c) = (b) - (a)	**+21**	**+26**
Total Currently Approved Annual Cost (d)	$43,945	$60,489
Total Annual Cost for Respondents in CY 2023 PFS final rule (e) (See Table 69, row (n))	$46,116	$63,177
Difference (f) = (e) - (d)	**+$2,171**	**+$2,688**

(5) Survey Vendor Requirements

The following proposed changes associated with CAHPS survey vendors to submit data for eligible clinicians will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We note that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to § 414.1400(d) for the requirements for CMS-approved survey vendors that may submit data on the CAHPS for MIPS Survey.

In this rule, we are adjusting the estimated number of vendors that will apply to participate as CAHPS for MIPS Survey vendors that were previously approved in the CY 2018 Quality Payment Program final rule (82 FR 53908). We estimate that we will receive approximately 10 survey vendor applications for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 5 survey vendor applications from our currently approved estimate of 15 vendors in the CY 2018 QPP final rule (82 FR 53908). As shown in Table 71, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 10 hours. This will result in an estimated annual

burden of 100 hours (10 survey vendor applications × 10 hr/application) at a cost of $10,340 (10 applications × $1,034/application)).

TABLE 71: Estimated Burden for Survey Vendor Requirements

Burden and Respondent Descriptions	Burden Estimate
# of Survey Vendor Applications (a)	10
# of Hours Per Computer Systems Analyst (b)	10
Total Annual Hours (c) = (a) * (b)	**100**
Cost to Submit a Survey Vendor Application (computer systems analyst @ $103.40/hr) (d)	$1,034
Total Annual Cost (e) = (a) * (d)	**$10,340**

In Table 72, we illustrate the net change in estimated burden for survey vendor requirements using the currently approved burden in the CY 2018 QPP final rule (82 FR 53908). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents participating as CAHPS for MIPS Survey vendors would result in a total annual adjustment of -50 hours (-5 responses × 10 hr/application) at a cost of -$5,170 (-5 × (10 hr × $103.40/hr)) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 72: Change in Estimated Burden for Survey Vendor Requirements

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	150
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 71, row (d))	100
Difference (c) = (b) - (a)	**-50**
Total Currently Approved Annual Cost (d)	$15,510
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 71, row (i))	$10,340
Difference (f) = (e) - (d)	**-$5,170**

d. ICRs Regarding Open Authorization (OAuth) Credentialing and Token Request Process

This rule is not proposing any new or revised collection of information requirements or burden related to the OAuth credentialing and token request process. The requirements and burden for the OAuth credentialing and token request process are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the OAuth credentialing and token burden under that control number.

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77502 through 77503 and 82 FR 53908 through 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60000 through 60003, 84 FR 63121 through 63124, 85 FR 84970 through 84974, 86 FR 65576 through 65588, and 87 FR 70145 through 70154, respectively) for our previously finalized estimated burden associated with data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: those who submit data as MIPS eligible clinicians, and those who submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the third snapshot date for the 2022 QP Performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2024 performance period/2026 MIPS payment year. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future for the CY 2024 performance period/2026 MIPS payment year (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the CY 2019 performance period/2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83

FR 59752). We note in this proposed rule, we are using the same CY 2021 performance period/2023 MIPS payment year submissions data used in the 2023 PFS Final Rule (87 FR 70145 through 70148).

We assume 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2021, CY 2022 and CY 2023 PFS final rules (85 FR 84972, 86 FR 65567 and 87 FR 70145), we include all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section V.B.11.a.(4) of this proposed rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the CY 2024 performance period/2026 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2021 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2019 performance period/2021 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their reporting as a group or individual for the CY 2021 performance period/2023 MIPS payment year.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The associated burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this proposed rule because sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[334]

For the CY 2024 performance period/2026 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, and eCQMs. Additionally, we capture the burden for clinicians who choose to submit via these collection types for the quality performance category of MVPs. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintaining consistency with previous rulemaking.

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the CY 2021 performance period/2023 MIPS payment year. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 73 uses methods similar to those described above to estimate the number of MIPS eligible clinicians that will submit data as individual clinicians via each collection type in the CY 2024 performance period/2026 MIPS payment year. For the CY 2024 performance period/2026 MIPS payment year, we estimate approximately 14,402 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 11,197 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 17,944 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2021 performance period/2023 MIPS payment year, these are decreases of 334, 261, and 418 respondents from the currently approved estimates of 14,736, 11,458, and 18,362 for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, respectively.

[334] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

TABLE 73: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2024 MIPS performance period (excludes QPs) (a)	16,746	13,020	20,865	50,632
MVP Adjustment @ 14% (b) = (a)* 0.14	-2,344	-1,823	-2,921	-7,091
2024 MIPS Performance Period (excludes QPs and Adjusted for MVP) (c)= (a) – (b)	**14,402**	**11,197**	**17,944**	**43,541**
**Currently approved 2023 MIPS Performance Period (excludes QPs) (d)	14,736	11,458	18,362	44,556
Difference (e) = (c) – (d)	**-334**	**-261**	**-418**	**-1,015**

* We estimate 14 percent of clinicians will participate in MVP reporting as discussed in section V.11.e.(7) of this rule.

**Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 73 are not mutually exclusive.

Table 74 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2024 performance periods/2026 MIPS payment year. We assume clinicians who submitted quality data as groups in the CY 2021 performance period/2023 MIPS payment year will continue to submit quality data either as groups, or virtual groups for the same collection types for the 2024 performance period/2026 MIPS payment years. We used the same methodology described in the CY 2022 PFS final rule (86 FR 65577) on our assumptions related to the use of an alternate collection type for groups that submitted data via the CMS Web Interface collection type for the CY 2021 performance period/2023 MIPS payment year.

As shown in Table 74, for the CY 2024 performance period/2026 MIPS payment year we estimate 6,312 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type and 5,402 groups and virtual groups will submit for eCQM collection types. These are decreases of 146 and 125 respondents from the currently approved estimates of 6,458, and 5,527 for the groups and virtual groups that will submit data using MIPS CQM and QCDR, and eCQM collection types, respectively.

As the data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM entities, we assume non-ACO APM Entities will participate through traditional MIPS and base our estimates on submissions received in the CY 2021 performance period/2023 MIPS payment year.

TABLE 74: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	Total
2024 MIPS performance period (excludes QPs) (a) prior to adjustments	0	7,339	6,281	13,620
Adjustment for MVPs (14%) (b) = (a) * 0.14	0	-1,027	-879	-1,906
2024 MIPS performance period (excludes QPs and) Adjusted for MVP). (c) = (a) – (b)	0	**6,312**	**5,402**	**11,714**
**Currently approved 2023 MIPS performance period (excludes QPs) (d)	0	6,458	5,527	11,985
Difference (e) = (d) - (c) - (d)	0	**-146**	**-125**	**-271**

* We estimate 12 percent of clinicians will participate in MVP reporting as discussed in section V.B.11.e.7. of this rule.

**Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

The burden associated with the submission of quality performance category data has some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their Electronic Health Record (EHR) implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. Additionally, as finalized in the CY 2022 PFS final rule (86 FR 65394 through 65397), group TINs could also choose to participate as subgroups for MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to the CY 2022 PFS final rule for additional details on MVP quality reporting requirements (86 FR 65411 through 65412).

In terms of the quality measures available for clinicians and groups to report for the CY 2024 performance period/2026 MIPS payment year, we propose a measure set of 200 quality measures. The new MIPS quality measures proposed for inclusion in MIPS for the CY 2024 performance period/2026 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 75, as well as counts of new, removed, and substantively changed measures. There are no changes to the remaining measures not included in Appendix 1. We refer readers to Appendix 1: MIPS Quality Measures of this proposed rule for additional information.

TABLE 75: Summary of Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year

Collection Type	# Measures Proposed as New	# Measures Proposed for Removal*	# Measures Proposed with a Substantive Change*	# Measures Proposed for CY 2024*
Medicare Part B Claims	0	-4	10	26
MIPS CQMs Specifications	+13	-11	51	174
eCQM Specifications	+1	-3	26	45
Survey – CSV	0	0	0	1
Administrative Claims	0	0	0	4
Total*	+14	-12**	59	200

*A measure may be specified under multiple collection types but will only be counted once in the total.
**We are proposing to remove 12 MIPS quality measures and partially remove 3 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs. NOTE: The 3 MIPS quality measures that are proposed for partial removal from traditional MIPS are not included in the total number of measures proposed for removal from MIPS starting with the CY 2024 performance period.

For the CY 2024 performance period/2026 MIPS payment year, we are proposing 200 measures, a net increase of 2 quality measures across all collection types compared to the currently approved estimate of 198 measures. Specifically, as discussed in section IV.A.4.f.(1)(e) of this rule, we are proposing to add 14 new MIPS quality measures, remove 12 MIPS quality measures, partially remove 3 MIPS quality measures that are proposed for removal from traditional MIPS and proposed for retention for use in MVPs, and make substantive updates to 59 MIPS quality measures. We do not anticipate our provision to remove these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures.

(3) Quality Payment Program Identity Management Application Process

This rule does not propose any new or revised collection of information requirements or burden related to the identity management application process. The identity management application process requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes for the identity management application process under that control number.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

This rule does not propose any new or revised collection of information requirements or burden related to the submission of Medicare Part B claims data for the quality performance category. Our updated estimate for MVP participation due to policy changes to the MVP inventory as discussed in section IV.A.4.a. of this rule, impacts the number of clinicians submitting quality data for MIPS using the Medicare Part B Claims-based collection type. We refer readers to Table 79 of this section for the change in associated burden related to the submission of Medicare Part B claims data for the MVP quality performance category in the CY 2024 performance period/2026 MIPS payment year.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77501 through 77504 and 82 FR 53912, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60004 through 60005, 84 FR 63124 through 63126, 85 FR 84975 through 84976, 86 FR 65582 through 65584, and 87 FR 70149 through 70151 respectively) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 73, we estimate that 14,402 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type, a decrease of 334 from the currently approved estimate of 14,736 (87 FR 70150).

In Table 76, consistent with our currently approved per response time figures and using the updated wage rates in Table 54 of this proposed rule, we continue to estimate the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $15.51 (0.15 hr × $103.40) for a computer systems analyst to 7.2 hours at a cost of $744.48 (7.2 hr × $103.40/hr). The burden also accounts for the effort needed to become familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time estimates and using the updated wage rates in Table 54 of this proposed rule, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours for a medical and health services manager at $123.06/hr, 1 hour for a physician at $274.44/hr, 1 hour for an LPN at $53.72/hr, 1 hour for a computer systems analyst at $103.40/hr, and 1 hour for a billing and posting clerk at $43.08/hr.

In Table 76, considering both data submission and start-up requirements for our adjusted number of clinicians, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In aggregate, the total annual time for the CY 2024 performance period/2026 MIPS payment year ranges from 102,974 hours (7.15 hr × 14,402 clinicians) to 204,508 hours (14.2 hr × 14,402 clinicians). The total annual cost for the CY 2024 performance period/2026 MIPS payment year ranges from a

minimum of $12,376,071 to a maximum of $22,874,697.

TABLE 76: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	14,402	14,402	14,402
Hours Per Computer Systems Analyst to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	**102,974**	**115,936**	**204,508**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr @ varying times) (j)	$15.51	$108.57	$744.48
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr @ 3 hr) (k)	$369.18	$369.18	$369.18
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr @ 1 hr) (l)	$103.40	$103.40	$103.40
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr @1 hr) (m)	$53.72	$53.72	$53.72
Cost to Review Measure Specifications (@ billing clerk's labor rate of $43.08/hr @ 1 hr) (n)	$43.08	$43.08	$43.08
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr @ 1 hr) (o)	$274.44	$274.44	$274.44
*Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$859.33	$952.39	$1,588.30
*Total Annual Cost (q) = (a) * (p)	**$12,376,071**	**$13,716,321**	**$22,874,697**

In Table 77, we used the currently approved burden as the baseline to calculate the net burden for the quality data submissions from clinicians using the Medicare Part B Claims-based collection type. In aggregate, using our currently approved per response time estimates, the decrease in number of responses from 14,736 to 14,402 (−334) results in a total maximum adjustment of −4,743 hours (−334 responses × 14.2 hr/response) at a cost of −$530,492 (−334 response × $1,588.30/response). For purposes of calculating total burden associated with this proposed rule as shown in Tables 99 through 101, only the maximum burden is used.

TABLE 77: Burden Adjustments for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	209,251
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (see Table 76, row (i))	204,508
Difference (c) = (b) - (a)	**-4,743**
Total Currently Approved Annual Cost (d)	$23,405,189
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (see Table 76, row (q)	$22,874,697
Difference (f) = (d) - (e)	**-530,492**

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77504 through 77505 and 82 FR 53912 through 53914, respectively), the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60005 through 60006, 84 FR 63127 through 63128, 85 FR 84977 through 84979, 86 FR 65584 through 65586, and 87 FR 70151 through 70153, respectively) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. We refer readers to Table 74 for the estimated change in associated burden for quality data submission using MIPS CQM and QCDR collection types related to MVP and subgroup reporting in the CY 2024 performance period/2026 MIPS payment year.

As noted in Tables 73 and 74, based on data from the CY 2021 performance period/2023 MIPS payment year, for the CY 2024 performance period/2026 MIPS payment year, we assume that 17,509 clinicians (11,197 individuals and 6,312 groups and virtual groups) will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. This is a decrease of 407 clinicians from the currently approved estimate of 17,916 clinicians provided in the CY 2023 PFS final rule (87 FR 70152). Given the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third party intermediary to submit the data to us on the clinician's or group's behalf. We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe the burden for an individual clinician or group to review measure specifications and submit quality data is a total of 9 hours at a cost of $1,039.54 per response. This consists of 3 hours at $103.40/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $123.06/hr for a medical and health services manager, 1 hour at $103.40/hr for a computer systems analyst, 1 hour at $53.72/hr for a LPN, 1 hour at $43.08/hr for a billing clerk, and 1 hour at $274.44/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hr) at $103.40/hr for a computer systems analyst at a cost of $8.15 (0.083 hr × $103.40/hr). Overall, we estimate 9.083 hr/response (3 hr + 2 hr + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hr) at a cost of $1,039.54/response [(3 hr × $103.40/hr) + (2 hr × $123.06/hr) + (1 hr × $274.44/hr) + (1 hr × $103.40/hr) + (1 hr × $53.72/hr) + (1 hr × $43.08/hr) + (0.083 hr × $103.40/hr)].

In Table 78, for the CY 2024 performance period/2026 MIPS payment year, in aggregate, we estimate a burden of 159,034 hours [9.083 hr/response × 17,509 responses] at a cost of $18,201,306 (17,509 responses × $1,039.54/response).

TABLE 78: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	11,197
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	6,312
Total # of Respondents (c) = (a) + (b)	**17,509**
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physician Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c)*(k)	**159,034**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr) (m)	$310.20
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (n)	$246.12
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr) (o)	$103.40
Cost LPN Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (p)	$53.72
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $43.08/hr) (q)	$43.08
Cost Physician Review Measure Specifications (@ physician's labor rate of $274.44/hr) (r)	$274.44
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $103.40/hr) (s)	$8.58
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$1,039.54
Total Annual Cost (u) = (c) * (t)	**$18,201,306**

In Table 79, we calculated the net change in estimated burden for quality performance category submissions using the MIPS CQM and QCDR collection type by using the currently approved burden in the CY 2023 PFS final rule (87 FR 70151 through 70153). In aggregate, using the unchanged currently approved time per response estimate, the decrease of 407 respondents from 17,916 to 17,509 for the CY 2024 performance period/2026 MIPS payment year results in a decrease of 3,697 hours (-407 responses $\times$ 9.083 hr/response) at a cost of $-$$423,093 (-407 responses $\times$ $1,039.54/response).

TABLE 79: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	162,731
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (see Table 78, row (l))	159,034
Difference (c) = (b) - (a)	**-3,697**
Total Currently Approved Annual Cost (d)	$18,624,399
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (see Table 78, row (u))	$18,201,306
Difference (f) = (e) - (d)	**-423,093**

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77505 through 77506 and 82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), CY 2020 PFS final rule (84 FR 63128 through 63130), CY 2021 PFS final rule (85 FR 84979 through 84980), the CY 2022 PFS final rule (86 FR 65586 through 65588), and the CY 2023 PFS final rule (87 FR 70153 through 70154) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2024 performance period/2026 MIPS payment year, we refer readers to Table 84.

Based on updated data from the CY 2022 performance period/2024 MIPS payment year data, we assume that 23,346 clinicians will submit quality data using the eCQM collection type for the CY 2024 performance period/2026 MIPS payment year. This is a decrease of 543 clinicians from the estimate of 23,889 clinicians provided in the CY 2023 PFS final rule (87 FR 70153). We assume the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their certified EHR technology (CEHRT) and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $103.40/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $123.06/hr for a medical and health services manager, 1 hour at $274.44/hr for a physician, 1 hour at $103.40/hr for a computer systems analyst, 1 hour at $53.72/hr for an LPN, and 1 hour at $43.08/hr for a billing clerk. Overall, we estimate a cost of $927.56/response [(2 hr × $103.40/hr) + (2 hr × $123.06/hr) + (1 hr × $274.44/hr) + (1 hr × $103.40/hr) + (1 hr × $53.72/hr) + (1 hr × $43.08/hr)].

In Table 80, for the CY 2024 performance period/2026 MIPS payment year, in aggregate, we estimate a burden of 186,768 hours [8 hr × 23,346 responses] at a cost of $21,654,816 (23,346 responses × $927.56/response).

TABLE 80: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	17,944
# of Groups submitting via EHR on behalf of individual clinicians (b)	5,402
Total # of Respondents (c)=(a)+(b)	**23,346**
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Physicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	**186,768**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr) (l)	$206.80
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (m)	$246.12
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr) (n)	$103.40
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (o)	$53.72
Cost to Review Measure Specifications (@ clerk's labor rate of $43.08/hr) (p)	$43.08
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr) (q)	$274.44
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$927.56
Total Annual Cost (s) = (c) * (r)	**$21,654,816**

In Table 81, we illustrate the net change in burden for submissions in the quality performance category using the eCQM collection type from the currently approved burden in the CY 2023 PFS final rule (87 FR 70153 through 70154). In aggregate, using our currently approved time per response burden estimate, the decrease of 543 respondents from 23,889 to 23,347 for the CY 2024 performance period/2026 MIPS payment year results in a decrease of 4,344 hours (−543 responses × 8 hr/response) at a cost of −$503,665 (−543 responses × $927.56/response).

TABLE 81: Burden Adjustments for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	191,112
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (see Table 80, row (k))	186,768
Difference (c) = (b) - (a)	**-4,344**
Total Currently Approved Annual Cost (d)	$22,158,481
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (see Table 80, row (s))	$21,654,816
Difference (f) = (e) - (d)	**-$503,665**

(7) ICRs Regarding Burden for MVP Reporting

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

(a) Burden for MVP Reporting Requirements

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022 and CY 2023 PFS final rules for our previously finalized burden assumptions and requirements for submission data for the MVP performance category, and for the estimated number of clinicians participating as subgroups in the CY

2023 performance period/2025 MIPS payment year (86 FR 65590 through 65592 and 87 FR 70155).

In section IV.A.4.b. of this rule, we are proposing to add five new MVPs to the MVP Inventory. Additionally, we are proposing to consolidate the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP. Therefore, MVP participants will have a total of sixteen MVPs available for the CY 2024 performance period/2026 MIPS payment year. Due to the availability of new MVPs, we expect an increase in the projected number of MVP participants. For each newly proposed MVP, we calculated the average quality measure submission rate across the measures available in each MVP for the CY 2021 performance period/2023 MIPS payment year. The total of these average quality measure submissions for each MVP was equivalent to about 2 percent of total quality measure submissions in the CY 2021 performance period/2023 MIPS payment year. We assume there would not be any changes to MVP submissions due to the proposed consolidation of the measures in the Promoting Wellness and Optimizing Chronic Disease Management MVPs into a Value in Primary Care MVP, discussed in section IV.A.4.b. of this rule. That is, we assume clinicians who would have submitted the Optimizing Chronic Disease Management MVP or the Promoting Wellness MVP would instead submit the Value in Primary Care MVP. Therefore, we estimate that 14 percent of the clinicians will participate in MVP reporting in the CY 2024 performance period/2026 MIPS payment year. This is an increase of 2 percentage points from the currently approved estimate of 12 percent in the CY 2023 PFS final rule (87 FR 70155). We refer readers to Appendix 3: MVP Inventory of this proposed rule for additional details on the MVPs proposed for the CY 2024 performance period/2026 MIPS payment year.

We assume the changes to the existing MVPs and the addition of new MVPs will not impact the currently approved number of subgroups. We expect clinician participation in subgroups will be relatively low for the CY 2024 performance period/2026 MIPS payment year due the voluntary subgroup reporting option and the additional burden involved for groups to organize clinicians into subgroups. Therefore, we did not make any adjustments to our previously finalized assumption in the CY 2023 PFS final rule (87 FR 70155) of 20 subgroups that will participate in MVP reporting.

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

We refer readers to the CY 2023 PFS final rule (87 FR 70155 through 70156) for our previously finalized burden relevant to MVP registration for clinicians participating as an individual and/or group for MVP reporting.

As previously discussed, we estimate that approximately 14 percent of the clinicians that currently participate in MIPS will submit data for the measures and activities in an MVP. For the CY 2024 performance period/2026 MIPS payment year, we assume that the total number of individual clinicians, groups, subgroups and APM Entities that will complete the MVP registration process is 9,015. In Table 82, we estimate that it will take 2,254 hours (9,015 responses × 0.25 hr/response) at a cost of $233,038 (9,015 registrations × $25.85/registration) for individual clinicians, groups and APM Entities to register for MVPs in the CY 2024 performance period/2026 MIPS payment year.

TABLE 82: Estimated Burden for MVP Registration (Individual clinicians, Groups, Subgroups and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Estimated # of Individual clinicians, groups, subgroups and APM Entities Registering (a)	9,015
Estimated Time Per Registration (hr) (b)	0.25
Estimated Total Annual Time (hr) for MVP Registration (c) = (a) * (b)	**2,254**
Computer systems analyst's labor rate ($/hr). (d)	103.40
Estimated Cost Per Registration (e) = (d) * (b)	25.85
Estimated Total Annual Cost for MVP Registration (f) = (a) * (e)	**$233,038**

In Table 83, we illustrate the net change in burden for MVP registration using the currently approved burden in the CY 2023 PFS final rule (87 FR 70155 through 70156). In aggregate, for the CY 2024 performance period/2026 MIPS payment year, the adjustment in the number of respondents expected to register for MVP reporting from 7,731 to 9,015 results in an increase of 1,284 responses. In aggregate, when combined with the currently approved per response time estimate, this will result in an increase of 321 hours (2,254 hours − 1,933 hours) at a cost of $33,192 ($233,038 − $199,846).

TABLE 83: Burden Adjustment for MVP Registration: Individuals, Groups, and APM Entities

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	1,933
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 82, row (c))	2,254
Difference (c) = (b) - (a)	**321**
Total Currently Approved Annual Cost (d)	$199,846
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 82, row (e))	$233,038
Difference (f) = (e) - (d)	**$33,192**

(ii) Burden for Subgroup Registration

We are not proposing any changes to our previously finalized subgroup registration burden. We note that the proposed subgroup policies in section IV.A.4.d. of this rule do not impact the currently approved burden for subgroup registration. We discuss in detail below, the proposed policies and our reasons for not changing the currently approved burden for subgroup registration. The burden relevant to the subgroup registration requirement is currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes pertaining to subgroup registration under that control number.

In section IV.A.4.d.(2) of this rule, we are proposing to modify § 414.1365(e)(2)(ii) to read that, an MVP Participant that is a subgroup will receive the same reweighting that is applied to its affiliated group, but that for the CY 2023 MIPS performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the circumstances independent of the affiliated group as described in § 414.1365(e)(2)(ii)(A) and (B). We believe that the proposed modification to the subgroup reweighting policy would not impact the currently approved burden for subgroup registration because it would not change any requirements related to subgroup registration.

In section IV.A.4.d.(3) of this rule, we are proposing to modify the text at § 414.1365(e)(3) to read that if an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). Additionally, we are proposing to add § 414.1365(e)(4)(i) to read that for subgroups, the affiliated group's complex patient bonus will be added to the final score. The proposed revisions would not impact the currently approved burden for subgroup registration since these changes only modify the regulatory text relevant to subgroup scoring policies.

In section IV.A.4.d.(4) of this rule, we are proposing to modify § 414.1385(a)(1) to read that a MIPS eligible clinician, subgroup, or group (including their designated support staff), or a third-party intermediary as defined at § 414.1305, may submit a request for a targeted review. The proposed change would not impact the currently approved burden for subgroup registration since the addition of subgroups to the targeted review language only modifies the regulatory text relevant to the targeted review process and does not change the subgroup registration requirements. We finalized in the CY 2017 Quality Payment Program final rule that a MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year (81 FR 77546). We note that information collection requirements, such as targeted reviews, that are imposed after an administrative action are not subject to the PRA under 5 CFR 1320.4(a)(2). Therefore, we are not making any adjustments to the currently approved subgroup registration burden because of the proposal to add subgroups to the targeted review regulation text.

(iii) Burden for MVP Quality Performance Category Submission.

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we previously finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i). As discussed in section V.B.11.e. of this rule, we did not propose new requirements to submit data for the quality performance category of MVPs. Therefore, we did not propose any changes to our currently approved per response time estimates for submitting the MVP quality performance category data.

As described in section V.B.11.e.(7)(a) of this proposed rule, we estimate that 14 percent of the clinicians who participated in MIPS for the CY 2021 performance period/2023 MIPS payment year will submit data for the quality performance category of MVP in the CY 2024 performance period/2026 MIPS payment year. We also estimate there will be 20 subgroup reporters in the CY 2024 performance period/2026 MIPS payment year. In Table 84, we estimate that 3,801 clinicians and 10 subgroups will submit data using eCQMs collection type at $614.45/response (see line q for eCQMs); 2,850 clinicians and 10 subgroups will submit data using MIPS CQM and QCDR collection type at $683.73/response (see line q for CQM and QCDRs); and 2,344 clinicians and 0 subgroups will submit data for the MVP quality performance category using the Medicare Part B claims collection type at $1,055.70/response (see line q for claims). For the CY 2024 performance period/2026 MIPS payment year, using our currently approved per response time estimates for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 20,198 hours [5.3 hr × 3,811 (3,801 +10) responses] at a cost of $2,341,669 (3,811 responses × $614.45/response) for the eCQM collection type, 17,074 hours [5.97 hr × 2,860 (2,443 +10)] at a cost of $1,955,468 (2,860 responses × $683.73/responses) for the

MIPS CQM and QCDR collection type, and 18,974 hours (9.44 hr × 2,344 clinician responses) at a cost of $2,474,561 (2,344 responses × $1,055.70/response) for the Medicare Part B claims collection type.

TABLE 84: Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from pre-existing collection types (a)	3,801	2,850	2,344
# of Subgroup reporters (b)	10	10	0
Total MVP participants (c) = (a) + (b)	3,811	2,860	2,344
Hours Per Computer Systems Analyst to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) * (j)	**20,198**	**17,074**	**22,127**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $103.40/hr @ varying times) (k)	$137.52	$206.80	$496.32
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $123.06/hr) (l)	$163.67	$163.67	$246.12
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $103.40/hr) (m)	$68.24	$68.24	$68.24
Cost to Review Measure Specifications (@ LPN's labor rate of $53.72/hr) (n)	$35.46	$35.46	$35.46
Cost to Review Measure Specifications (@ billing clerk's labor rate of $43.08/hr) (o)	$28.43	$28.43	$28.43
Cost to Review Measure Specifications (@ physician's labor rate of $274.44/hr) (p)	$181.13	$181.13	$181.13
*Total Annual Cost Per Submission (q) = (k) + (l) + (m) + (n) + (o) + (p)	$614.45	$683.73	$1,055.70
***Total Annual Cost (r) = (c) * (q)**	**$2,341,669**	**$1,955,468**	**$2,474,561**

Table 85 illustrates the proposed changes in estimated burden for clinicians who will submit the MVP quality performance category utilizing the eCQM, MIPS CQM and QCDR, and claims collection types in the CY 2024 performance period/2026 MIPS payment year. We note we used the currently approved burden in the CY 2023 PFS final rule (87 FR 70157 through 70159) as the baseline to determine the net change in burden. In aggregate, when combined with our currently approved per response time estimate, the increase in 1,284 respondents who will submit data for the MVP quality performance category will result in an increase of 2,878 hours and $333,633 for the eCQM collection type, an increase of 2,430 hours and $278,273 for the CQM and QCDR collection type, and an increase of 3,153 hours and $352,599 for the claims collection type.

TABLE 85: Burden Adjustments for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
Total Currently Approved Annual Hours (a)	17,320	14,644	18,974
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 84, row (k))	20,198	17,074	22,127
Difference (c) = (b) - (a)	**2,878**	**2,430**	**3,153**
Total Currently Approved Annual Cost (d)	$2,008,036	$1,677,195	$2,121,962
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 84, row (r))	$2,341,669	$1,955,468	$2,474,561
Difference (f) = (e) - (d)	**$333,633**	**$278,273**	**$352,599**

(8) Beneficiary Responses to CAHPS for MIPS Survey

The following proposed changes associated with CAHPS survey vendors to submit data for eligible clinicians will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We note that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to the CY 2021 Quality Payment Program final rule (85 FR 84982 through 84983) for our previously finalized estimated burden associated with beneficiary responses to the CAHPS for MIPS Survey.

In section IV.A.4.f.(1)(c)(ii) of this proposed rule, we are proposing to require Spanish language administration of the CAHPS for MIPS Survey. Specifically, we are proposing to require organizations to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, will administer the Spanish survey translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. For requirements and burden, we estimate an average administration time of 13.1 minutes (or 0.2183 hr) at a pace of 4.5 items per minute for the English version of the survey. For the Spanish version, we estimate an average administration time of 15.7 minutes (assuming 20 percent more words in the Spanish translation). However, since less than 1 percent of surveys were administered in Spanish for the CY 2022 performance period, we are not updating our burden estimates to include the time associated with the Spanish version at this time.

In this rule, we are adjusting the estimated number of beneficiaries that will respond to the CAHPS for MIPS survey from the previously approved number of beneficiaries in the CY 2021 PFS final rule (85 FR 84982 through 84983). For the CY 2024 performance period/2026 MIPS payment year, we are estimating that 100 groups will elect to report on the CAHPS for MIPS survey. Based on the number of complete and partially complete surveys for groups participating in CAHPS for MIPS survey administration for the CY 2022 performance period/2024 MIPS payment year, we estimate that an average of 255 beneficiaries will respond per group for the CY 2024 performance period/2026 MIPS payment year. Therefore, we estimate that the CAHPS for MIPS survey will be administered to approximately 25,500 beneficiaries for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 4,452 beneficiary respondents from our currently approved estimate of 29,952 beneficiary respondents in the CY 2021 PFS final rule (85 FR 84982). As shown in Table 86, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time to administer the survey is 0.2183 hours. This will result in an estimated annual burden of 5,567 hours at a cost of $165,750.

TABLE 86: Estimated Burden for Beneficiary Response Requirements

Burden and Respondent Descriptions	Burden Estimate
# of Groups Practices Administering CAHPS for MIPS Survey (a)	100
# of Beneficiaries Per Group Responding to Survey (b)	255
# of Total Beneficiaries Reporting (c)=(a)*(b)	25,500
# of Hours Per Beneficiary Respondent (d)	0.2183
Total Annual Hours (e) = (c) * (d)	**5,567**
Cost for Beneficiary to Respond to CAHPS for MIPS Survey @ labor rate of $29.76/hr (f) = (d) *$29.76/hr	$6.50
Total Annual Cost (g) = (e) * (f)	**$165,750**

In Table 87, we illustrate the net change in estimated burden for beneficiary response requirements using the currently approved burden in the CY 2021 PFS final rule (85 FR 84982 through 84983). In aggregate, using our

currently approved per response time estimate, the decrease in the number of respondents submitting responses for the CAHPS for MIPS survey results in a total annual adjustment of −972 hours at a cost of −$28,938 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 87: Change in Estimated Burden for Beneficiary Response Requirements

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	6,539
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 81, row (e))	5,567
Difference (c) = (b) - (a)	**-972**
Total Currently Approved Annual Cost (d)	$194,688
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 81, row (g))	$165,750
Difference (f) = (e) - (d)	**-$28,938**

(9) Group Registration for CAHPS for MIPS Survey

The following proposed changes will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We note that the associated burden will be made available for public review and comment under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

We refer readers to CY 2019 PFS final rule (83 FR 60009 through 60010) for the previously approved requirements and burden for group registration for the CAHPS for MIPS Survey.

In this rule, we are adjusting the estimated number of groups registering for the CAHPS for MIPS Survey that were previously approved in the CY 2019 PFS final rule (83 FR 60009 through 60010) based on updated data from the CY 2022 performance period/2024 MIPS payment year. We estimate that 266 groups will register for the CAHPS for MIPS Survey for the CY 2024 performance period/2026 MIPS payment year. This adjustment will result in a decrease of 16 group registrations from our currently approved estimate of 282 groups in the CY 2019 PFS final rule (83 FR 60010). In Table 88, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 0.75 hours. This will result in an estimated annual burden of 200 hours (266 groups × 0.75 hr/registration) at a cost of $20,628 (266 registrations × $77.55/registration) for a computer systems analyst).

TABLE 88: Estimated Burden for Group Registration for the CAHPS for MIPS Survey

Burden and Respondent Descriptions	Burden Estimate
# of Groups Registering for the CAHPS for MIPS Survey (a)	266
# of Hours Per Computer Systems Analyst (b)	0.75
Total Annual Hours (c) = (a) * (b)	**200**
Cost to Register a Group for the CAHPS for MIPS Survey (@ computer systems analyst @ $103.40/hr) (d) = (b) *$103.40/hr	$77.55
Total Annual Cost (e) = (c) * (d)	**$20,628**

In Table 89, we illustrate the net change in estimated burden for groups registering for the CAHPS for MIPS Survey using the currently approved burden in the CY 2019 PFS final rule (83 FR 60009 through 60010). In aggregate, using our currently approved per response time estimate, the decrease in the number of respondents registering for the CAHPS for MIPS Survey from 282 to 266 results in a total annual adjustment of −12 hours (−16 responses × 0.75 hr/nomination) at a cost of −$1,241 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 89: Change in Estimated Burden for Group Registration for the CAHPS for MIPS Survey

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	212
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 88, row (c))	200
Difference (c) = (b) - (a)	**-12**
Total Currently Approved Annual Cost (d)	$21,869
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 88, row (i))	$20,628
Difference (f) = (e) - (d)	**-$1,241**

f. ICRs Regarding the Call for MIPS Quality Measures

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

This rule does not propose any new or revised collection of information requirements or burden related to the call for MIPS quality measures. However, based on the actual number of quality measure submissions received for CMS consideration during the 2023 Annual Call for Quality Measures, we are adjusting our burden estimates for the CY 2024 performance period/2026 MIPS payment year.

In this rule, we estimate we will receive 31 quality measure submissions during the 2023 Annual Call for Quality Measures, an increase of 2 from the currently approved number of quality measure submissions for consideration (87 FR 70159 through 70160). We are not proposing any changes to the 5.5 hour (2.4 hr for practice administrator + 3.1 hr for clinician) per response time estimate for quality measure submissions.

In Table 90, we estimate an annual burden of 171 hours (31 measure submissions × 5.5 hr/measure) at a cost of $35,529 (31 measure submissions × $1,146.11/submission for the CY 2024 performance period/2026 MIPS payment year.

TABLE 90: Estimated Burden for Call for Quality Measures

Burden and Respondent Descriptions	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	31
# of Hours per Practice Administrator to Identify, Propose and Link Measure (b)	2.4
# of Hours per Clinician to Identify and Link Measure (c)	1.1
# of Hours per Clinician to Complete Peer Review Article Form (d)	2
Annual Hours Per Response (e) = (b) + (c) + (d)	5.5
Total Annual Hours (f)=(a)*(e)	**171**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $123.06/hr) * 2.4 hr = (g)	$295.34
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ clinician's labor rate of $274.44/hr) * 3.1 hr = (h)	$850.77
Total Annual Cost Per Submitted Measure (i) = (g) + (h)	$1,146.11
***Total Annual Cost (j)=(a)*(i)**	**$35,529**

In Table 91, we illustrate the net change in estimated burden for the call for quality measures using the currently approved burden in the CY 2023 PFS final rule (87 FR 70159 through 70160). In aggregate, the estimated increase in the number of quality measure submissions will result in an adjustment of +11 hours (+2 measure submissions × 5.5 hr/measure submission) at a cost of $2,292 (+2 measure submissions × $1,146.11/measure submission) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 91: Burden Adjustments for Call for Quality Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours for Respondents (a)	160
Total Annual Hours for Respondents in CY 2023 PFS Final Rule (b) (See Table 85, row (f))	171
Difference (c) = (b) - (a)	**+11**
Total Currently Approved Annual Cost for Respondents (d)	$33,237
Total Annual Cost for Respondents in CY 2024 PFS Proposed Rule (e) (See Table 85, row (j))	$35,529
Difference (f) = (e) - (d)	**+$2,292**

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2024 performance period/2026 MIPS payment year, MIPS eligible clinicians, groups, subgroups, and APM Entities can submit Promoting Interoperability performance category data through direct log in and upload, or log in and attest submission types. We note that the log in and attest submission type is only available for the Promoting Interoperability performance category and is not available for the quality performance category. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, we anticipate that MIPS eligible individual clinicians, groups, subgroups, and APM Entities will use the same data submission type for both the quality and Promoting Interoperability performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. We note that this analysis assesses burden by performance category and submission type and emphasizes that MIPS is a consolidated program. We analyze data submitted by MIPS eligible clinicians, groups, subgroups and APM Entities, and assesses clinician performance based on all the four MIPS performance categories, as applicable.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The following proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77240 through 77243), CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60011 through 60012, 84 FR 63134 through 63135, 85 FR 84984 through 84985, 86 FR 65596 through 65598, and 87 FR 70160 through 70162, respectively) for our previously finalized requirements for, and our analysis of the information collection and reporting burden associated with, reweighting applications for Promoting Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians may submit an application requesting reweighting to zero percent for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances as set forth in § 414.1380(c)(2), including, but not limited to, extreme and uncontrollable circumstances and significant hardship or other type of exception (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Table 92 summarizes our analysis of the estimated burden for MIPS eligible clinicians to apply for reweighting of the Promoting Interoperability performance category to zero percent due to a significant hardship or other exception as provided in § 414.1380(c)(2)(i)(C).

Respondents (MIPS eligible individual clinicians, groups, or APM Entities) who apply for a reweighting of the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting of the Promoting Interoperability performance category on the same online form. We assume respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances (for example, PHE for COVID–19, vendor issues, etc.) will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

In section IV.A.4.f.(4)(f) of this rule, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for clinical social workers for the CY 2024 performance period/2026 MIPS payment year and making the corresponding revisions to the regulatory text at § 414.1380(c)(2)(i)(A)(*4*)(*iii*). In our analysis of the information collection and reporting burden, we are not adjusting our estimated number of respondents submitting reweighting applications due to this proposal because these proposed changes only modify the regulatory text and do not change the existing reweighting policy for these clinician types participating in MIPS in the CY 2024 performance period/2026 MIPS payment year. To further clarify, these clinician types are automatically reweighted for the Promoting Interoperability performance category and do not need to submit a reweighting application, and therefore do not impact our information collection and reporting burden analysis.

Based on the number of reweighting applications received at the time of the publication of this rule for the CY 2022 performance period/2024 MIPS payment year, we are adjusting our burden estimates relevant to this ICR. In this proposed rule, we estimate that we will receive a total of 29,227 applications to request reweighting for any or all the four MIPS performance categories for the CY 2024 performance

period/2026 MIPS payment year. Out of the 29,227, we estimate that 2,706 respondents will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship or other exception as provided in § 414.1380(c)(2)(i)(C). We estimate the remaining 26,510 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activities performance categories due to an extreme or uncontrollable circumstance. Additionally, we estimate 11 APM Entities will submit an extreme and uncontrollable circumstances exception application for the CY 2024 performance period/2026 MIPS payment year. This adjustment results in an increase of 23,788 respondents compared to our currently approved estimate of 5,439 respondents (87 FR 70161). This increase is based on the actual number of reweighting applications submitted for the CY 2022 performance period/2024 MIPS payment year. We note this estimate reflects the significant increase in the number of submitted applications due to extending the deadline, as a result of the ongoing PHE for COVID–19 at the time, for submitting the reweighting applications for the CY 2022 performance period/2024 MIPS payment year to March 3rd, 2023.

Consistent with our assumptions in the CY 2023 PFS final rule (87 FR 70160 through 70162), we continue to estimate it will take 0.25 hours for a computer system analyst to complete and submit the reweighting application. In Table 92, we estimate an annual burden of 7,307 hours (29,227 applications × 0.25 hr/application) at a cost of $755,518 (29,227 applications × $25.85/application).

TABLE 92: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	29,216
# APM Entities requesting Extreme and Uncontrollable Circumstances exception (b)	11
Total Applications Submitted (c)	**29,227**
Annual Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (c) * (d)	**7,307**
Cost to Submit a Reweighting Application @ computer systems analyst's labor rate of $103.40/hr (f) = (d) *$103.40/hr	$25.85
Total Annual Cost (g) = (e) * (f)	**$755,518**

In Table 93, we illustrate the proposed net change in estimated burden for submission of reweighting applications for Promoting Interoperability and other performance categories using the currently approved burden in the CY 2023 PFS final rule (87 FR 70160 through 70162). The proposed adjustment in the estimated number of respondents, from 5,439 to 29,227 respondents, results in an increase of 23,788 respondents. In aggregate, using our currently approved per response time estimate, as shown in Table 93, the proposed increase in 23,788 respondents results in an increase of 5,947 hours (+23,788 responses × 0.25 hr/response) and $614,920 (+5,947 hr × $103.40/hr) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 93: Change in Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2023 PFS final rule (a)	1,360
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 92, row (c))	7,307
Difference (c) = (b) - (a)	**+5,947**
Total Currently Approved Annual Cost in CY 2023 PFS final rule (d)	$140,598
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 92, row (e))	$755,518
Difference (f) = (e) - (d)	**+$614,920**

(3) Submitting Promoting Interoperability Data

We are not proposing any new or revised collection of information requirements or burden related to the submission of Promoting Interoperability performance category data. We note the policy proposals in section IV.A.4.f.(4) of this rule related to the submission of Promoting Interoperability data do not impact the currently approved estimated burden for

this ICR. We discuss in detail below the proposed policies and our reasons for not changing our currently approved burden for submission of Promoting Interoperability data. The submission of Promoting Interoperability data requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any submission of Promoting Interoperability changes under that control number.

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77509 through 77511, and 82 FR 53919 through 53920, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (83 FR 60013 through 60014, 84 FR 63135 through 63137, 85 FR 84985 through 84987, 86 FR 65598 through 65600, and 87 FR 70162 through 70164, respectively) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In section IV.A.4.f.(4)(b)of this proposed rule, we are proposing that for the CY 2026 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 180-day period within CY 2024, up to and including the full CY 2024 (January 1, 2024, through December 31, 2024). We are proposing to modify the Promoting Interoperability performance category performance period that we established under § 414.1320(h)(1) to remove subsequent years, include the 2025 MIPS payment year, and add § 414.1320(i)(1) to reflect our proposal. We assume MIPS eligible clinicians and groups that currently submit data for the Promoting Interoperability performance category would utilize the CEHRT for an entire calendar year performance period and therefore, the proposed increase in the length of the performance period for the Promoting Interoperability performance category from 90 to 180 days would not create additional burden for MIPS eligible clinicians and groups that would submit data for the Promoting Interoperability performance category. We note that this is consistent with the discussion of burden for the above policy in the FY 2022 IPPS final rule (86 FR 45515).

In section IV.A.4.f.(4)(d)(i)of this rule, we are proposing changes to the Query of Prescription Drug Monitoring Program Measure under the Electronic Prescribing Objective. Specifically, we are proposing to modify the second exclusion criterion to state that any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period can claim the second exclusion. The proposed changes would not affect the requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category since the revision is meant to revise the previously finalized second exclusion in the CY 2018 Quality Payment Program final rule (82 FR 53679). Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

In section IV.A.4.f.(4)(d)(ii) of this rule, we are proposing to revise the e-Prescribing measure description in Table 45 to read ''At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT'' and the numerator will be updated to read to indicate ''Number of prescriptions in the denominator generated and transmitted electronically'' to reflect the removal of the health IT certification criterion ''drug-formulary and preferred drug list checks.'' These proposed revisions would not affect the requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category since these changes provide technical updates to the e-prescribing measure. Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

In section IV.A.4.f.(4)(d)(iii)of this rule, we are proposing to modify our requirements for the SAFER Guides measure beginning with the CY 2024 performance period/2026 MIPS payment year and subsequent years, to require MIPS eligible clinicians conduct, and therefore attest ''yes'' an annual self-assessment of the CEHRT using the High Priority Practices SAFER Guide (*available at https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs. We note we have captured the estimated burden for reporting this measure in the CY 2022 PFS final rule (86 FR 65599) and the proposed revision would not affect the data collection and submission requirements for MIPS eligible clinicians and groups that submit data for the Promoting Interoperability performance category. Therefore, we are not making any adjustments to our currently approved estimated burden for this ICR.

h. ICRs Regarding the Nomination of Promoting Interoperability Measures

The following proposed changes associated with the information collection related to the nomination of Promoting Interoperability measures will be submitted to OMB for review to remove the information collection relevant to the nomination of Promoting Interoperability measures under control number 0938–1314 (CMS 10621). This rule does create any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability performance category measures. Due to a consistent decline in the number of submissions received for the Promoting Interoperability performance category measures, we estimate to receive fewer than 10 responses for this ICR. Therefore, we are proposing to remove the ICR for nomination of Promoting Interoperability performance category measures.

As shown in Table 94, we estimate an annual burden of zero hours at a cost of $0 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 94: Estimated Burden for Call for Promoting Interoperability Measures

Burden and Respondent Descriptions	Burden Estimate
# of Organizations Nominating New Promoting Interoperability Measures (a)	0
# of Hours Per Medical and health services manager to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) [x] (d)	**0**
Cost to Identify and Submit Measure (@ medical and health services manager's labor rate of $123.06/hr.) (f) = (b) [x] $123.06/hr	$36.92
Cost to Identify Improvement Measure (@ physician's labor rate of $274.44/hr.) (g) = (c) [x] $274.44/hr	$54.89
Total Annual Cost Per Respondent (h) = (f) + (g)	$91.81
Total Annual Cost (i) = (a) [x] (h)	**$0**

In Table 95, we illustrate the proposed net change in estimated burden for nomination of Promoting Interoperability measures using the currently approved burden in the CY 2023 PFS final rule (87 FR 70163). The proposed removal of the ICR for nomination of Promoting Interoperability measures results in a decrease of 5 hours (-10 responses × 0.5 hr/response) and a decrease of $918 for the CY 2024 performance period/2026 MIPS payment year.

TABLE 95: Change in Estimated Burden for Nomination of Promoting Interoperability Measures

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours in CY 2023 PFS final rule (a)	5
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 94, row (c))	0
Difference (c) = (b) - (a)	**-5**
Total Currently Approved Annual Cost in CY 2023 PFS final rule (d)	$918
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 94, row (e))	0
Difference (f) = (e) - (d)	**-$918**

i. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

We are not proposing any new or revised collection of information requirements or burden related to the submission of improvement activity data. We note that the policy proposal in section IV.A.4.f.(3) of this proposed rule related to the improvement activities submission does not impact our currently estimated burden for this ICR. We discuss in detail below the proposed policy and reasons that it does not change our currently approved burden for improvement activities submission. The improvement activity submission requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any improvement activity submission changes under that control number.

In section IV.A.4.f.(3)(b)(ii) of this proposed rule, we are proposing changes to the improvement activities inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing four previously adopted improvement activities. We do not believe the changes will impact our currently approved time for interested parties to submit information because MIPS eligible clinicians are still required to submit the same number of activities and the estimated per response time for each activity is uniform. Therefore, we are not proposing to adjust our currently approved burden for improvement activities submission as a result of this proposal.

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The proposed changes associated with data submission will be submitted to OMB for review under control number 0938–1314 (CMS 10621).

In this rule, based on the actual number of respondents that submitted improvement activity nominations, we are proposing to adjust the estimated number of improvement activity nominations that were previously approved in the CY 2022 PFS final rule (86 FR 65603 through 65605). We estimate that we will receive approximately 15 improvement activity nominations for the CY 2024 performance period/2026 MIPS payment year. This adjustment will

result in a decrease of 16 improvement activity nominations from our currently approved estimate of 31 nominations in the CY 2022 PFS final rule (86 FR 65605). In Table 96, for the CY 2024 performance period/2026 MIPS payment year, we continue to estimate that the per response time is 4.4 hours. This will result in an estimated annual burden of 66 hours (15 nominations × 4.4 hr/nomination) at a cost of $11,755 (15 × [(2.8 hr × $123.06/hr for a medical and health services manager) + (1.6 hr × $274.44/hr for a physician)]).

TABLE 96: Estimated Burden for Nomination of Improvement Activities

Burden and Respondent Descriptions	Burden Estimate
# of Nominations of New IAs (a)	15
# of Hours Per Medical and Health Services Manager (b)	2.8
# of Hours Per Physician (c)	1.6
Annual Hours Per Respondent (d)= (b) + (c)	4.4
Total Annual Hours (e) = (a) * (d)	**66**
Cost to Nominate an IA (@ medical and health services manager's labor rate of $123.06/hr) (f) = (b) x $123.06/hr	$344.57
Cost to Nominate an IA (@ physician's labor rate of $274.44/hr) (g) = (c) x $274.44/hr	$439.10
Total Annual Cost Per Respondent (h) = (f) + (g)	$783.67
Total Annual Cost (i) = (a) * (h)	**$11,755**

In Table 97, we illustrate the proposed net change in estimated burden for nomination of improvement activities using the currently approved burden in the CY 2022 PFS final rule (86 FR 65605). In aggregate, using our currently approved per response time estimate, the proposed decrease in the number of respondents submitting improvement activity nominations results in a total annual adjustment of -70 hours (-16 responses × 4.4 hr/nomination) at a cost of -$12,539 (-16 x [(2.8 hr × $123.06/hr) + (1.6 hr × $274.44/hr)]) for the CY 2024 performance period/2026 MIPS payment year.

TABLE 97: Change in Estimated Burden for Nomination of Improvement Activities

Burden and Respondent Descriptions	CY 2024 Performance Period
Total Currently Approved Annual Hours (a)	136
Total Annual Hours for Respondents in CY 2024 PFS proposed rule (b) (See Table 94, row (d))	66
Difference (c) = (b) - (a)	**-70**
Total Currently Approved Annual Cost (d)	$24,294
Total Annual Cost for Respondents in CY 2024 PFS proposed rule (e) (See Table 94, row (i))	$11,755
Difference (f) = (e) - (d)	**-$12,539**

k. Nomination of MVPs

This rule does not propose any new or revised collection of information requirements or burden related to the nomination of MVPs. The requirements and burden for nomination of MVPs are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the nomination of MVPs under that control number.

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the policies in this rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not making any changes under that control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule is not proposing any new or revised collection of information requirements or burden related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. The requirements and burden for Partial QP Elections are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to Partial QP Elections under that control number.

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information

requirements related to Other Payer Advanced APM determinations.

(1) Payer-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements related to the Payer-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the Payer-Initiated process under that control number.

(2) Eligible Clinician-Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements or burden related to the Eligible Clinician-Initiated Process. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the Eligible Clinician-Initiated Process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule is not proposing any new or revised collection of information requirements or burden related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden for the All-Payer Combination option are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Compare Tools (§ 414.1395)

This rule is not proposing any new or revised collection of information requirements or burden related to the election by voluntary participants to opt-out of public reporting on Compare Tools. The requirements and burden associated with this information collection are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to the election of voluntary participants to opt-out of performance data display on Compare Tools under that control number.

p. Summary of Annual Quality Payment Program Burden Estimates

Table 99 summarizes this proposed rule's total burden estimates for the Quality Payment Program for the CY 2024 performance period/2026 MIPS payment year.

In the CY 2023 PFS final rule, the total estimated burden for the CY 2024 performance period/2026 MIPS payment year (see Table 99, row a) was 710,644 hours at a cost of $75,687,130 (87 FR 70169). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2023 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year is 626,007 hours at a cost of $70,778,884 (see Table 99, row b). These represent a decrease of 84,637 hours and a decrease of $4,908,246. To understand the burden implications of the policies in this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year. This burden estimate of 630,570 hours at a cost of $71,317,983 (see Table 99, row c) reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflects the exclusion of QPs from all MIPS performance categories, an increase of 4,563 hours and $539,099 (see Table 99, row d). This burden estimate is higher than the burden approved for information collection related to the CY 2023 PFS final rule due to updated data and assumptions. Our total burden estimate for the CY 2024 performance period/2026 MIPS payment year is 626,568 hours and $70,858,430 (see Table 99, row e), which represents an increase of 561 hours and $79,546 from the CY 2023 PFS final rule (see Table 99, row f). The difference of −4,002 hours (561 hours − 4,563 hours) and −$459,553 ($79,546 − $539,099) (see Table 99, row g) between this estimate and the total burden shown in Table 99 is the decrease in burden associated with impacts of the policies for the CY 2024 performance period/2026 MIPS payment year.

TABLE 98: Summary of Burden Estimates and Requirements from the CY 2024 PFS Proposed Rule

CY 2024 Performance Period/2026 MIPS Payment Year		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2023 PFS Final Rule (a)	710,644	$75,687,130
CY 2023 PFS Final Rule w/ updated wage rates and ICRs (b)	626,007	$70,778,884
CY 2023 PFS Final Rule w/ updated data and assumptions (c)	630,570	$71,317,983
Change in burden due to updated data and assumptions (d) = (c) – (b)	**4,563**	**$539,099**
CY 2024 PFS Proposed Rule Total Burden (e)	626,568	$70,858,430
Total change in burden (as shown in Table D-A43) (f) = (e) – (b)	561	$79,546
Change in burden associated with policies (g) = (f) – (d)	**-4,002**	**-$459,553**

TABLE 99: Summary of Quality Payment Program Burden Estimates and Requirements CMS-10621 (OMB 0938-1314) and CMS-10450 (OMB 0938-1222)

Requirement	Currently Approved Responses	CMS-1784-P Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1784-P Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR simplified self-nomination (see Tables 60 and 61)	0	45	+45	0	365	+365
§ 414.1400 QCDR full self-nomination (see Tables 63 and 63)	63	10	-53	636	101	-535
§ 414.1400 Registry simplified self-nomination (see Tables 64 and 65)	0	89	+89	0	45	+45
§ 414.1400 Registry full self-nomination (see Tables 66 and 67)	132	36	-96	264	72	-192
§ 414.1400 Third Party Intermediary Plan Audits (see Tables 69 and 70)	127	130	+3	585	611	+26
§ 414.1400 Survey Vendor Requirements (see Tables 71 and 72)	15	10	-5	150	100	-50
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see Tables 76 and 77)	14,736	14,402	-334	209,251	204,508	-4,743
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see Tables 78 and 79)	17,916	17,509	-407	162,731	159,034	-3,697
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see Tables 80 and 81)	23,889	23,346	-543	191,112	186,768	-4,344
§414.1365 MVP Registration (see Tables 82 and 83)	7,731	9,015	+1,284	1,933	2,254	+321
MVP Quality Submission (see Tables 84 and 85)	7,731	9,015	+1,284	50,938	59,399	+8,461
§§ 414.1325 and 414.1335	29,952	25,500	-4,452	6,539	5,567	-972

Requirement	Currently Approved Responses	CMS-1784-P Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1784-P Total Time (Hours)	Change in Total Time (Hours)
Beneficiary Responses for CAHPS for MIPS Survey (see Tables 86 and 87)						
Group Registration for CAHPS for MIPS Survey (see Tables 88 and 89)	282	266	-16	212	200	-12
Call for Quality Measures (see Tables 90 and 91)	29	31	+2	160	171	+11
§ 414.1380(c)(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Tables 92 and 93)	5,439	29,227	+23,788	1,360	7,307	+5,947
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see Tables 94 and 95)	31	15	-16	136	66	-70
TOTAL	108,073	128,646	+20,573	626,007	626,568	+561

Table 100 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this proposed rule. We have divided the reasons for our change in burden into those related to proposed policies in the CY 2024 PFS rule and those related to adjustments in burden continued from the CY 2023 PFS final rule policies that reflect updated data and revised methods.

TABLE 100: Reasons for Proposed Change in Burden Compared to the Currently Approved CY 2023 Information Collection Burden

ICR Title	Changes in burden due to CY 2024 proposed rule policies	Adjustments in burden continued from CY 2023 PFS final rule policies due to revised methods or updated data
QCDR Simplified Self-Nomination and other Requirements (See Table 61)	None	Proposed addition of a new ICR.
QCDR Full Self-Nomination and other Requirements (See Table 63)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Qualified Registry Simplified Self-Nomination and other Requirements (See Table 65)	None	Proposed addition of a new ICR.
Qualified Registry Full Self-Nomination and other Requirements (See Table 67)	None	Decrease in number of respondents due to updated assumptions. Decrease in the total number of hours due to restructuring the ICR.
Third Party Intermediary Plan Audits (see Table 70)	None	New ICR. Increase in number of respondents and hours due to updated assumptions for the CY 2024 performance period/2026 MIPS payment year.
Survey Vendor Requirements (see Table 72)	None	Decrease in number of respondents due to updated assumptions.
Quality Performance Category: Medicare Part B Claims Collection Type (see Table 77)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the claims collection type.	None
Quality Performance Category: QCDR/ MIPS CQM Collection Type (see Table 79)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the QCDR and MIPS CQM collection type.	None
Quality Performance Category: eCQM Collection Type (see Table 81)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the eCQM collection type.	None
MVP Registration (see Table	Increase in number of	None

ICR Title	Changes in burden due to CY 2024 proposed rule policies	Adjustments in burden continued from CY 2023 PFS final rule policies due to revised methods or updated data
83)	respondents due to finalized addition of 5 new MVPs.	
MVP Quality Submission (see Table 85)	Increase in number of respondents due to finalized addition of 5 new MVPs.	None
Beneficiary Responses for CAHPS for MIPS Survey (see Table 87)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Group Registration for CAHPS for MIPS Survey (see Table 89)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Call for Quality Measures (see Table 91)	None	Increase in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year
Promoting Interoperability Performance Category: Reweighting Applications for Promoting Interoperability and Other Performance Categories (see Table 93)	None	Increase in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year.
Improvement Activities Performance Category: Nomination of Improvement Activities (see Table 95)	None	Decrease in number of respondents due to updated projections for the CY 2024 performance period/2026 MIPS payment year

C. Summary of Annual Burden Estimates for Changes

TABLE 101: Annual Requirements and Burden Estimates

Section(s) Under Title 42 of the CFR	OMB Control Number	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 414.940 (Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts)	0938-1435 (CMS-10835	25 in the initial year; 2 in subsequent years	25 in the initial year, 2 in subsequent years	5	125 in the initial year, 10 in subsequent years	41.74	5,218 in the initial year; 418 in subsequent years
§ 414.94(c)(2) (AUC Program Provider-Led Entity reapplication for qualification)	0938-1288 (CMS-10570)	(10)	(10)	(15)	(150)	(1,714.2)	(17,142)
Placeholder RHC/FQHC CfCs	0938-0344 (CMS-R-38)						
§§ 600.125(a)(1), 600.140(b)(4) through (6), 600.145(a), 600.145(f)(2), and 600.170(a)(2) Basic Health Program (BHP) Provisions	0938-1218 (CMS-10510)	2	varies	varies	356	varies	30,322
§§414.1325 and 414.1335 Quality Payment Program: CAHPS Survey	0938-1222 (CMS-10450)	(4,473)	(4,473)	Varies	(1,034)	Varies	(35,349)
§§ 414.1318, 414.1325 and 414.1335, 414.1360, 414.1365, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 Quality Payment Program	0938-1314 (CMS-10621)	+25,036	+25,036	Varies	+1,590	Varies	+113,880
TOTAL				Varies		Varies	

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed in this section, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** section of this proposed rule and identify the rule (CMS–1784–P) the ICR's CFR citation, and OMB control number.

VI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

In this proposed rule, we are proposing payment and policy changes under the Medicare PFS and required statutory changes under the Consolidated Appropriations Act, 2021 (CAA, 2021); sections 301, 302, 303, 304, and 305 under the Consolidated Appropriations Act, 2022 (CAA, 2022); sections 2003 and 2005 of the SUPPORT for Patients and Communities Act of 2018, sections 4113, 4114, and 4121 under the Consolidated Appropriations Act of 2023 (CAA, 2023), section 90004 of the Infrastructure Investment and Jobs Act, section 6 of the Sustaining Excellence in Medicaid Act of 2019, and sections 11101, 11402, 11403, 11407 under the Inflation Reduction Act (IRA). Our policies in this rule specifically address: changes to the PFS; other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; updates and refinements to Medicare Shared Savings Program (Shared Savings Program) requirements; updates to the Quality Payment Program; updates to the Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; updates to electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act); changes to the regulations associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System; and changes to release Medicare Advantage risk adjustment data early for use with Care Compare websites. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Extension of Certain Medicare Telehealth Flexibilities, Under Section 1834(m) of the Act, as Amended by the CAA, 2023

Section II.D.1.e. of this proposed rule implements section 4113, of the CAA, 2023, which extended through CY 2024 several temporary flexibilities for Medicare telehealth services adopted during the PHE for COVID–19. Specifically, section 4113 extended the

temporary inapplicability of geographic and location restrictions, extended the temporary expansion of practitioner types who can be paid for Medicare telehealth services, delayed the in-person visit requirements for mental health services furnished via telehealth, and extended audio-only flexibilities for certain telehealth services. This provision is necessary to fulfill the statutory requirement to implement this extension through December 31, 2024.

b. Drugs and Biological Products Paid Under Medicare Part B

Section III.A.1. of this proposed rule proposes regulations text changes to implement provisions of the Inflation Reduction Act of 2022 that affect payment amounts or patient out-of-pocket costs for certain drugs and biologicals payable under Part B. Two provisions affect payment amounts for biosimilar biological products. Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024 during the initial period when ASP data is not available. Section 11403 makes changes to the payment limit for certain biosimilar products with an ASP that is not more than the ASP of the reference biological for a period of 5 years. Two other provisions make statutory changes to patient out-of-pocket costs for certain drugs payable under Medicare Part B. Section 11101 of the IRA requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. Section 11407 makes statutory changes to waive the deductible for insulin that is furnished through a covered item of durable medical equipment (DME) and establishes a $35 cap on cost sharing for a month's supply of insulin furnished through a covered item of DME, both beginning July 1, 2023.

Section III.A.3 of this proposed rule proposes policies to implement section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (IIJA) which requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. These provisions are necessary to fulfill the statutory requirement to implement this policy effective January 1, 2023 and reduce unnecessary Medicare spending for discarded drug.

c. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Section III.B.2. of this proposed rule implements sections 4113, 4121, and 4124 of the CAA, 2023. Section 4113 of the CAA, 2023 amends section 1834(m)(8) of the Act to extend payment for telehealth services furnished by RHCs and FQHCs for the limited period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024. Section 4113 also delays the in-person requirements under Medicare for mental health visits furnished by RHCs and FQHCs via telecommunications technology until January 1, 2025.

Section 4121 of the CAA, 2023 amends section 1861(aa)(1)(B) of the Act by adding marriage and family therapists (MFT) and mental health counselors (MHC) as eligible practitioners of RHCs and FQHCs beginning January 1, 2024. Section 4121 allows MFTs and MHCs to bill directly and be paid as an RHC and FQHC practitioner under the RHC AIR an FQHC PPS.

Section 4124 of the CAA, 2023 establishes an Intensive Outpatient benefit in RHCs and FQHCs. Proposals related to implementation of IOP for RHCs and FQHCs are discussed in the CY 2024 OPPS proposed rule.

d. Clinical Laboratory Fee Schedule (CLFS)—Proposed Revisions Consistent With Recent Statutory Changes

Section III.D.5. of this rule proposes conforming regulations text changes for CLFS data reporting requirements due to the enactment of section 4114 of the CAA, 2023. For clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), the CAA, 2023 delays the next data reporting period by one year. Instead of taking place from January 1, 2023 through March 31, 2023, data reporting will now take place from January 1, 2024 through March 31, 2024, based on the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests then resumes on a 3-year cycle (2027, 2030, etc.). Additionally, the CAA, 2023 amends the statutory provisions for the phase-in of payment reductions resulting from private payor rate implementation to specify that the applicable percent in CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. The CAA, 2023 further amends the statutory phase-in provisions to provide that for CYs 2024 through 2026, the payment amount for a CDLT may not be reduced by more than 15 percent as compared to the payment amount for that test established in the preceding year.

e. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In this rule, we are proposing changes to the electronic prescribing for controlled substances (EPCS) requirement specified in section 2003 of the SUPPORT Act (referred to as the CMS EPCS Program). The proposals specify the basis for the evaluation of compliance by describing how prescriptions are calculated, remove the same entity exception while conditioning the electronic prescribing requirement as subject to the exemption in § 423.160(a)(3)(iii), identify non-compliance actions for subsequent measurement years, and update other CMS EPCS Program exceptions. Previously finalized policies did not include actions for non-compliance after the 2024 measurement year, and we need to identify actions for non-compliance in subsequent measurement years.

f. Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System

Section 4103 of the CAA amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2024. The ambulance extender provisions are enacted through legislation that is self-implementing. We are proposing only to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

Section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. In this proposed rule, we are proposing revisions to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

g. Quality Payment Program

This proposed rule is also necessary to make changes to the Quality Payment Program to move the program forward to

focus more on measurement efforts, refine how clinicians will be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and highlight the value of participating in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. Currently, reporting for traditional MIPS is seen as siloed across the performance categories. These policy proposals are intended to promote better quality reporting to improve patient health outcomes by coordinating reporting for MIPS across performance categories, and make changes to scoring that will provide a better picture of clinicians' performance.

2. Discretionary Provisions

a. Drugs and Biological Products Paid Under Medicare Part B

In section III.A. of this proposed rule, as part of our continued implementation, section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (IIJA) which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. We are proposing the date of the initial report to manufacturers, the date for subsequent reports, method of calculation when there are multiple manufacturers for a refundable drug, increased applicable percentages for drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug.

b. RHCs and FQHCs

In section III.B.2. of this proposed rule, we are proposing to continue to define ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision of services and supplies furnished incident to a physician's service through December 31, 2024 for RHCs and FQHCs.

In section III.B.3. of this proposed rule, we are proposing to change the required level of supervision for behavioral health services furnished ''incident to'' a physician or non-physician practitioner's services at RHCs and FQHCs to allow general supervision, rather than direct supervision, consistent with the policies finalized under the PFS for CY 2023.

In section III.B.4. of this proposed rule, we are proposing a policy to include Remote Patient Monitoring (RPM), Remote Therapeutic Monitoring (RTM), Community Health Integration (CHI), and Principal Illness Navigation (PIN) services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. We are proposing to revise the calculation for G0511 to include the weighted average of these services using the CY 2021 PFS non-facility utilization. These provisions are necessary in that we evaluate coding provisions in this rule and their applicability to RHCs and FQHCs.

Also, in section III.B.4. of this proposed rule, we are proposing to remove the direct supervision requirement for obtaining consent for CCM services and virtual communication services furnished in RHCs and FQHCs.

c. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising Practitioners

In section III.E. of this proposed rule, we are proposing revisions to §§ 410.47 (PR) and 410.49 (CR/ICR) to add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). These provisions are necessary to fulfill the statutory requirement to implement these changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BBA of 2018) effective January 1, 2024.

d. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.F. of this proposed rule, we are proposing to allow periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the end of CY 2024, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met. We believe this modification is needed because extending these audio-only flexibilities for an additional year may minimize disruptions associated with the conclusion of the PHE, and evidence has shown that Medicare beneficiaries from historically underserved populations are more likely to be offered and use audio-only telemedicine services than audio-video services.[335] Therefore, minimizing disruptions to care for audio-only periodic assessments may further promote health equity and minimize disparities in access to care.

e. Medicare Shared Savings Program

In section III. G. of this proposed rule, we are proposing modifications to the Shared Savings Program to further advance Medicare's overall value-based care strategy of growth, alignment, and equity, and to respond to concerns raised by ACOs and other interested parties. The proposed changes to the Shared Savings Program include the following: modifications to the quality performance standard and reporting requirements under the APP that would continue to move ACOs toward digital measurement of quality and to align with QPP; modifications to the step-wise beneficiary assignment methodology to add a new third step and related changes to how we identify the assignable beneficiary population; updates to the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines; refinements to the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years to (1) cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth, (2) apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year, (3) further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high cost beneficiaries, and (4) specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations; refine newly established

[335] *https://pubmed.ncbi.nlm.nih.gov/33471458/.*

AIP policies; make updates to other programmatic areas including the program's eligibility requirements; and make timely technical changes to the regulations for clarity and consistency.

f. Medicare Part B Payment for Preventive Vaccine Administration Services

Section III.H.3 of this proposed rule discusses the implementation of policies that impact the payment amount for administration of preventive vaccines paid under the Part B vaccine benefit, specifically the proposed in-home additional payment for Part B vaccine administration. Section III.H.4. of this proposed rule codifies other amendments to the regulation text for Part B preventive vaccine administration. These provisions are necessary to provide stable payment for preventive vaccine administration and to allow predictability for providers and suppliers to rely on for building and sustaining robust vaccination programs.

g. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

In section III.J. of this proposed rule, we are proposing to pause implementation of the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94. These provisions are necessary because we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization.

h. Medicare and Medicaid Provider Enrollment

This proposed rule also proposes several regulatory enhancements to our Medicare and Medicaid provider enrollment policies. These provisions focus on, but are not limited to: (1) expanding the bases for denying or revoking a provider's or supplier's Medicare enrollment; (2) revising the effective dates of certain Medicare revocations; and (3) revising certain policies regarding Medicaid terminations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers and/or to increase the efficiency of the Medicare and Medicaid provider enrollment processes. We believe that fulfilling these objectives would assist in protecting the Trust Funds and Medicare beneficiaries.

i. Expand Diabetes Screening and Diabetes Definitions

In section III.L. of this proposed rule, we are proposing to (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test, (2) expand and simplify the frequency limitations for diabetes screening, and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, Medical Nutrition Therapy (MNT) and Diabetes Outpatient Self-Management Training Services (DSMT). Diabetes is a chronic disease that affects how the body turns food into energy and includes three main types: Type 1, Type 2 and gestational diabetes. The Centers for Disease Control and Prevention (CDC) reports that approximately 37.3 million Americans are living with diabetes and an additional 96 million Americans are living with prediabetes.[336] CDC reports that 326,000 persons age 65 years and older are newly diagnosed with diabetes each year. CDC also estimates that among persons age 65 years and older, 21 percent have been diagnosed with diabetes while 5 percent have undiagnosed diabetes.[337] Diabetes is the leading cause of kidney failure and new cases of blindness among adults, and the sixth leading cause of death among adults age 65 years and older in the US.[338] Screening is performed on persons who may not exhibit symptoms to identify persons with either prediabetes or diabetes, who can then be referred for appropriate prevention or treatment, with the intention of improving health outcomes.

j. Basic Health Program Provisions

Section 1331 of the ACA requires the Secretary to establish a BHP, and section 1331(c)(4) of the ACA specifically provides that a State shall coordinate the administration of, and provision of benefits under the BHP with other State programs. Additionally, section 1331(f) of the ACA requires the Secretary to review each State's BHP on an annual basis. These proposed regulations build from previous BHP regulations to provide for options for BHP implementation and operations as well as oversight of the BHP program, beginning with program year 2024.

k. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

In section III.S. of this proposed rule, we are proposing to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the Annual Wellness Visit (AWV) by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. We propose that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention plan. The AWV also provides an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months. The goals of AWV are health promotion, disease prevention and detection and include education, counseling, a health risk assessment, referrals for prevention services, and a review of opioid use. Additional information about the AWV can be found on the CMS website at (*https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html*).

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits

[336] CDC Website on diabetes at *https://www.cdc.gov/diabetes/basics/index.html.*

[337] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Accessed March 9, 2023. *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.*

[338] Heron M. Deaths: Leading causes for 2019. National Vital Statistics Reports; vol 70 no 9. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: *https://dx.doi.org/10.15620/cdc:107021.*

(including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)) as measured by the $200 million or more in any 1 year. Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, the PFS pays for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we discussed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement provisions of the statute. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives we considered, if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2023 with payment rates for CY 2024 using CY 2022 Medicare utilization. The payment impacts described in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally

furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2024, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments. In addition, the CAA, 2023 provided a one-time 2.50 percent increase in PFS payment amounts for services furnished on or after January 1, 2023, and a one-time 1.25 percent increase in PFS payment amounts for services furnished on or after January 1, 2024, and required that the supplementary increases shall not be taken into account in determining PFS payment rates for subsequent years.

To calculate the CY 2024 PFS conversion factor (CF), we took the CY 2023 conversion factor without the one-year 2.50 percent payment increase provided by the CAA, 2023 for CY 2023 and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs and the 1.25 percent PFS payment increase provided by the CAA, 2023 for CY 2024. We estimate the CY 2024 PFS CF to be 32.7476 which reflects the −2.17 percent budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the 1.25 percent payment increase for services furnished in CY 2024, as provided in the CAA, 2023. We estimate the CY 2024 anesthesia CF to be 20.4370 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 102: Calculation of the CY 2024 PFS Conversion Factor

CY 2023 Conversion Factor		33.8872
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		33.0607
CY 2024 RVU Budget Neutrality Adjustment	-2.17 percent (0.9783)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7476**

TABLE 103: Calculation of the CY 2024 Anesthesia Conversion Factor

CY 2023 National Average Anesthesia Conversion Factor		21.1249
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		20.6097
CY 2024 RVU Budget Neutrality Adjustment	-2.17 percent (0.9783)	
CY 2024 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.11 percent (1.0011)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**20.4370**

Table 104 shows the payment impact of the policies contained in this proposed rule on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 104 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 104.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2022 utilization and CY 2023 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated CY 2024 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2024 impact on total allowed charges of the changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated CY 2024 impact on total allowed charges of the changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated CY 2024 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 104: CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
ALLERGY/IMMUNOLOGY	$216	0%	-1%	0%	-1%
ANESTHESIOLOGY	$1,647	-2%	-1%	0%	-2%
AUDIOLOGIST	$69	-1%	-1%	0%	-2%
CARDIAC SURGERY	$174	-1%	-1%	0%	-2%
CARDIOLOGY	$5,989	0%	0%	0%	0%
CHIROPRACTIC	$644	-1%	-1%	0%	-2%
CLINICAL PSYCHOLOGIST	$711	1%	0%	0%	2%
CLINICAL SOCIAL WORKER	$795	2%	0%	0%	2%
COLON AND RECTAL SURGERY	$147	-1%	-1%	0%	-2%
CRITICAL CARE	$331	-1%	0%	0%	-1%
DERMATOLOGY	$3,713	0%	0%	0%	-1%
DIAGNOSTIC TESTING FACILITY	$828	0%	-2%	0%	-2%
EMERGENCY MEDICINE	$2,460	-2%	-1%	0%	-2%
ENDOCRINOLOGY	$507	1%	1%	0%	3%
FAMILY PRACTICE	$5,504	2%	2%	0%	3%
GASTROENTEROLOGY	$1,474	0%	0%	0%	0%
GENERAL PRACTICE	$361	1%	1%	0%	2%
GENERAL SURGERY	$1,614	-1%	-1%	0%	-1%
GERIATRICS	$180	0%	1%	0%	1%
HAND SURGERY	$251	-1%	0%	0%	-1%
HEMATOLOGY/ONCOLOGY	$1,591	1%	0%	0%	2%
INDEPENDENT LABORATORY	$546	-1%	-1%	0%	-1%
INFECTIOUS DISEASE	$573	-1%	0%	0%	-1%
INTERNAL MEDICINE	$9,618	0%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	$849	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$457	-1%	-3%	0%	-4%
MULTISPECIALTY CLINIC/OTHER PHYS	$146	0%	0%	0%	0%
NEPHROLOGY	$1,803	-1%	0%	0%	-1%
NEUROLOGY	$1,323	0%	0%	0%	1%
NEUROSURGERY	$694	-1%	0%	0%	-1%
NUCLEAR MEDICINE	$51	-1%	-2%	0%	-3%
NURSE ANES / ANES ASST	$1,081	-2%	0%	0%	-2%
NURSE PRACTITIONER	$6,260	1%	1%	0%	2%
OBSTETRICS/GYNECOLOGY	$558	0%	1%	0%	1%
OPHTHALMOLOGY	$4,647	0%	0%	0%	-1%
OPTOMETRY	$1,292	-1%	-1%	0%	-2%
ORAL/MAXILLOFACIAL SURGERY	$62	-1%	-1%	0%	-2%
ORTHOPEDIC SURGERY	$3,358	-1%	0%	0%	-1%
OTHER	$55	0%	-1%	0%	0%
OTOLARYNGOLOGY	$1,112	0%	0%	0%	0%
PATHOLOGY	$1,136	-1%	-1%	0%	-2%
PEDIATRICS	$55	0%	1%	0%	1%
PHYSICAL MEDICINE	$1,087	0%	0%	0%	-1%
PHYSICAL/OCCUPATIONAL THERAPY	$5,257	-1%	-2%	0%	-2%
PHYSICIAN ASSISTANT	$3,366	1%	1%	0%	2%
PLASTIC SURGERY	$300	-1%	-1%	0%	-1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
PODIATRY	$1,890	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	$75	0%	0%	0%	-1%
PSYCHIATRY	$897	1%	1%	0%	2%
PULMONARY DISEASE	$1,290	0%	0%	0%	0%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	$1,552	0%	-2%	0%	-2%
RADIOLOGY	$4,517	-1%	-2%	0%	-3%
RHEUMATOLOGY	$509	1%	1%	0%	2%
THORACIC SURGERY	$292	-1%	-1%	0%	-2%
UROLOGY	$1,623	0%	0%	0%	1%
VASCULAR SURGERY	$1,009	0%	-3%	0%	-3%
TOTAL	$88,549	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

In recent years, we have received requests from interested parties for CMS to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented high-level information to CMS suggesting that Medicare payment policies are directly responsible for the consolidation of privately-owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in the delivery of health care, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in last year's final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2024 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For this rulemaking cycle, we are providing an additional impact table that includes a facility/non-facility breakout of payment changes. The following is an explanation of the information represented in Table 105.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2022 utilization and CY 2023 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Combined Impact): This column shows the estimated CY 2024 combined impact on total allowed charges.

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TABLE 105: CY 2024 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$216	-1%
	Non-Facility	$209	-1%
	Facility	$7	2%
ANESTHESIOLOGY	*TOTAL*	$1,647	-2%
	Non-Facility	$314	-2%
	Facility	$1,332	-2%
AUDIOLOGIST	*TOTAL*	$69	-2%
	Non-Facility	$67	-2%
	Facility	$3	-2%
CARDIAC SURGERY	*TOTAL*	$174	-2%
	Non-Facility	$34	-2%
	Facility	$141	-2%
CARDIOLOGY	*TOTAL*	$5,989	0%
	Non-Facility	$3,712	1%
	Facility	$2,278	-1%
CHIROPRACTIC	*TOTAL*	$644	-2%
	Non-Facility	$643	-2%
	Facility	$1	-2%
CLINICAL PSYCHOLOGIST	*TOTAL*	$711	2%
	Non-Facility	$567	2%
	Facility	$143	1%
CLINICAL SOCIAL WORKER	*TOTAL*	$795	2%
	Non-Facility	$646	3%
	Facility	$149	2%
COLON AND RECTAL SURGERY	*TOTAL*	$147	-2%
	Non-Facility	$54	-1%
	Facility	$94	-2%
CRITICAL CARE	*TOTAL*	$331	-1%
	Non-Facility	$50	2%
	Facility	$281	-2%
DERMATOLOGY	*TOTAL*	$3,713	-1%
	Non-Facility	$3,575	-1%
	Facility	$137	0%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$828	-2%
	Non-Facility	$827	-2%
	Facility	$2	-3%
EMERGENCY MEDICINE	*TOTAL*	$2,460	-2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$193	-1%
	Facility	$2,267	-2%
ENDOCRINOLOGY	*TOTAL*	$507	3%
	Non-Facility	$406	3%
	Facility	$101	1%
FAMILY PRACTICE	*TOTAL*	$5,504	3%
	Non-Facility	$4,373	4%
	Facility	$1,131	1%
GASTROENTEROLOGY	*TOTAL*	$1,474	0%
	Non-Facility	$547	2%
	Facility	$927	-1%
GENERAL PRACTICE	*TOTAL*	$361	2%
	Non-Facility	$285	3%
	Facility	$76	-1%
GENERAL SURGERY	*TOTAL*	$1,614	-1%
	Non-Facility	$468	-1%
	Facility	$1,146	-2%
GERIATRICS	*TOTAL*	$180	1%
	Non-Facility	$105	2%
	Facility	$75	0%
HAND SURGERY	*TOTAL*	$251	-1%
	Non-Facility	$134	0%
	Facility	$118	-1%
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,591	2%
	Non-Facility	$1,037	1%
	Facility	$554	2%
INDEPENDENT LABORATORY	*TOTAL*	$546	-1%
	Non-Facility	$534	-1%
	Facility	$13	-3%
INFECTIOUS DISEASE	*TOTAL*	$573	-1%
	Non-Facility	$84	2%
	Facility	$489	-2%
INTERNAL MEDICINE	*TOTAL*	$9,618	1%
	Non-Facility	$4,699	3%
	Facility	$4,918	-1%
INTERVENTIONAL PAIN MGMT	*TOTAL*	$849	0%
	Non-Facility	$666	1%
	Facility	$183	-2%
INTERVENTIONAL RADIOLOGY	*TOTAL*	$457	-4%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$292	-5%
	Facility	$166	-3%
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$146	0%
	Non-Facility	$72	1%
	Facility	$74	-1%
NEPHROLOGY	*TOTAL*	$1,803	-1%
	Non-Facility	$1,068	0%
	Facility	$735	-2%
NEUROLOGY	*TOTAL*	$1,323	1%
	Non-Facility	$845	2%
	Facility	$477	-1%
NEUROSURGERY	*TOTAL*	$694	-1%
	Non-Facility	$119	0%
	Facility	$575	-2%
NUCLEAR MEDICINE	*TOTAL*	$51	-3%
	Non-Facility	$26	-2%
	Facility	$25	-3%
NURSE ANES / ANES ASST	*TOTAL*	$1,081	-2%
	Non-Facility	$24	-2%
	Facility	$1,057	-2%
NURSE PRACTITIONER	*TOTAL*	$6,260	2%
	Non-Facility	$4,036	3%
	Facility	$2,224	1%
OBSTETRICS/GYNECOLOGY	*TOTAL*	$558	1%
	Non-Facility	$381	2%
	Facility	$177	0%
OPHTHALMOLOGY	*TOTAL*	$4,647	-1%
	Non-Facility	$3,270	0%
	Facility	$1,377	-1%
OPTOMETRY	*TOTAL*	$1,292	-2%
	Non-Facility	$1,227	-2%
	Facility	$65	-1%
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$62	-2%
	Non-Facility	$51	-2%
	Facility	$11	-2%
ORTHOPEDIC SURGERY	*TOTAL*	$3,358	-1%
	Non-Facility	$1,480	0%
	Facility	$1,878	-1%
OTHER	*TOTAL*	$55	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$43	0%
	Facility	$12	-1%
OTOLARYNGOLOGY	*TOTAL*	$1,112	0%
	Non-Facility	$883	1%
	Facility	$230	-1%
PATHOLOGY	*TOTAL*	$1,136	-2%
	Non-Facility	$589	-1%
	Facility	$546	-3%
PEDIATRICS	*TOTAL*	$55	1%
	Non-Facility	$34	2%
	Facility	$21	-1%
PHYSICAL MEDICINE	*TOTAL*	$1,087	-1%
	Non-Facility	$535	1%
	Facility	$552	-2%
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$5,257	-2%
	Non-Facility	$5,257	-2%
	Facility	$	0%
PHYSICIAN ASSISTANT	*TOTAL*	$3,366	2%
	Non-Facility	$2,257	3%
	Facility	$1,109	0%
PLASTIC SURGERY	*TOTAL*	$300	-1%
	Non-Facility	$133	-1%
	Facility	$167	-2%
PODIATRY	*TOTAL*	$1,890	0%
	Non-Facility	$1,682	0%
	Facility	$208	0%
PORTABLE X-RAY SUPPLIER	*TOTAL*	$75	-1%
	Non-Facility	$72	-1%
	Facility	$3	-2%
PSYCHIATRY	*TOTAL*	$897	2%
	Non-Facility	$496	3%
	Facility	$401	0%
PULMONARY DISEASE	*TOTAL*	$1,290	0%
	Non-Facility	$532	3%
	Facility	$758	-2%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,552	-2%
	Non-Facility	$1,076	-2%
	Facility	$476	-2%
RADIOLOGY	*TOTAL*	$4,517	-3%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$1,977	-3%
	Facility	$2,540	-3%
RHEUMATOLOGY	*TOTAL*	$509	2%
	Non-Facility	$457	2%
	Facility	$52	3%
THORACIC SURGERY	*TOTAL*	$292	-2%
	Non-Facility	$57	-5%
	Facility	$235	-2%
UROLOGY	*TOTAL*	$1,623	1%
	Non-Facility	$1,150	1%
	Facility	$474	0%
VASCULAR SURGERY	*TOTAL*	$1,009	-3%
	Non-Facility	$724	-4%
	Facility	$284	-2%
TOTAL	***TOTAL***	$88,549	0%
	Non-Facility	$55,071	1%
	Facility	$33,478	-1%

2. CY 2024 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including family practice, endocrinology, nurse practitioner, physician assistant, clinical social worker, psychiatry, clinical psychologist, and general practice, reflect increases relative to other physician specialties. These increases can largely be attributed to proposed implementation of the separate payment for the O/O E/M visit inherent complexity add-on code, the Year 3 update to clinical labor pricing, and/or the proposed adjustment to certain behavioral health services. Approximately 90 percent of the budget neutrality adjustment is attributable to the O/O E/M visit inherent complexity add-on code with all other proposed valuation changes making up the other 10 percent. The services that make up these specialties rely primarily on E/M services, behavioral health care, or on clinical labor for their practice expense costs. These increases are also due to increases in value for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from updates to supply and equipment pricing.

The estimated impacts for several specialties, including anesthesiology, interventional radiology, radiology, vascular and thoracic surgery, physical/occupational therapy, and audiologists reflect decreases in payments relative to payment to other physician specialties, largely resulting from the redistributive effects of the implementation of separate payment for the O/O E/M visit inherent complexity add-on code, the Year 3 update to clinical labor pricing, and/or the proposed adjustment to certain behavioral health services. The services that make up these specialties were negatively affected by the redistributive effects of increases in work RVUs for other codes, and/or rely primarily on supply/equipment items for their practice expense costs and therefore were affected negatively by the updated Year 3 clinical labor pricing under budget neutrality. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreases due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 104), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 104 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for

the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

As discussed above, we have reviewed our suite of public use files and have worked on new ways to offer interested parties additional information that addresses some of the concerns raised about lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2022 utilization data, Total RVUs change between −1 percent and 1 percent for more than 15 percent of practitioners, representing approximately 26 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Specialties, such as gastroenterology, exhibit little variation in changes in total RVUs per practitioner. Table 104 (CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty) indicates an overall change of 0 percent for this specialty, and the practitioner-level distribution shows that 89 percent of these practitioners will experience a change in Total RVUs between −2 percent and 2 percent. The specific service mix within a specialty may vary by practitioner, so individual practitioners may experience different changes in total RVUs. For example, Table 104 indicates a 1 percent increase in RVUs for the internal medicine specialty as a whole, however, 49 percent of internal medicine specialty practitioners—representing over 41 percent of Total RVUs for the specialty—will experience a 1 percent or more decrease in Total RVUs. Meanwhile, 40 percent of internal medicine specialty practitioners will experience 2 percent or more increases in Total RVUs, and these practitioners account for a similar 41 of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule.

The specialty impacts displayed in Table 104 reflect changes that take place within the pool of total RVUs. The specialty impacts table therefore includes any changes in spending which result from finalized policies within BN (such as the updated proposals associated with the complexity add-on code G2211 in CY 2024 or the clinical labor pricing update that began in CY 2022) but does not include any changes in spending which result from finalized policies that are not subject to BN adjustment, and therefore, have a neutral impact across all specialties. The 2.50 and 1.25 percent payment supplements for CY 2023 and CY 2024, respectively, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table 104.

b. Impact

Column F of Table 104 displays the estimated CY 2024 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2024 PFS proposed rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.* We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

3. Health Equity

Advancing health equity is the first pillar of CMS's 2022 Strategic Framework.[339] As part of our efforts to gain insight into how the PFS policies could affect health equity, we are considering adding elements to our impact analysis which would detail how policies impact particular patient populations. Patient populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes, people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency, members of rural communities, and persons otherwise adversely affected by persistent poverty or inequality.

In the FY 2024 IPPS/LTCH PPS proposed rule, (88 FR 27261 through 27266), we included a table that details providers in terms of the beneficiaries they serve, as well as differences in estimated average payments per case and changes in estimated average payments per case relative to other providers. Because we do not have data for all characteristics that may identify disadvantaged or underserved patient populations, we use several proxies to capture these characteristics, including elements from claims data and Medicare enrollment data. The characteristics included in the table in the IPPS/LTCH PPS proposed rule, described in further detail below, include race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low income subsidy (LIS) enrollment, a joint indicator for dual or LIS enrollment, presence of an ICD–10–CM Z code indicating a ''social determinant of health'' (SDOH), presence of a behavioral health diagnosis code, receiving end-stage renal disease (ESRD) Medicare coverage, qualifying for Medicare due to disability, living in a rural area, and living in an area with an area deprivation index (ADI) greater than or equal to 85.

a. Race and Ethnicity

The first health equity-relevant grouping is race/ethnicity. To assign the race/ethnicity variables, we utilized the Medicare Bayesian Improved Surname Geocoding (MBISG) data in conjunction with the claims data. The method used to develop the MBISG data involves estimating a set of six racial and ethnic probabilities (White, Black, Hispanic, American Indian or Alaska Native, Asian or Pacific Islander, and multiracial) from the surname and address of beneficiaries by using previous self-reported data from a national survey of Medicare beneficiaries, post-stratified to CMS enrollment files. The MBISG method is used by the CMS Office of Minority Health in its reports analyzing Medicare Advantage plan performance on Healthcare Effectiveness Data and Information Set (HEDIS) measures, and is being considered by CMS for use in other CMS programs. In the 2024 IPPS/LTCH proposed rule (88 FR 27261 through 27266), we estimated the percentage of discharges for each specified racial/ethnic category for each hospital by taking, the sum of the probabilities for that category for that hospital and dividing by the hospital's total number of discharges.

b. Income

The two main proxies for income available in the Medicare claims and enrollment data are dual eligibility for Medicare and Medicaid and Medicare LIS status. Dual-enrollment status is a powerful predictor of poor outcomes on

[339] Available at *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

some quality and resource use measures even after accounting for additional social and functional risk factors.[340] Medicare LIS enrollment refers to a beneficiary's enrollment in the low-income subsidy program for the Part D prescription drug benefit. This program covers all or part of the Part D premium for qualifying Medicare beneficiaries and gives them access to reduced copays for Part D drugs. (We note that beginning on January 1, 2024, eligibility for the full low-income subsidy will be expanded to include individuals currently eligible for the partial low-income subsidy.) Because Medicaid eligibility rules and benefits vary by State/territory, Medicare LIS enrollment identifies beneficiaries who are likely to have low income but may not be eligible for Medicaid. Not all beneficiaries who qualify for the duals or LIS programs actually enroll. Due to differences in the dual eligibility and LIS qualification criteria and less than complete participation in these programs, sometimes beneficiaries were flagged as dual but not LIS or vice versa. Hence this analysis also used a ''dual or LIS'' flag as a third proxy for low income. The dual and LIS flags were constructed based on enrollment/eligibility status in the CMS Chronic Conditions Data Warehouse (CCW) during the month of the hospital discharge.

c. Social Determinants of Health (SDOH)

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[341] These circumstances or determinants influence an individual's health status and can contribute to wide health disparities and inequities. ICD–10–CM contains Z-codes that describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation. The presence of ICD–10–CM Z-codes in the range Z55–Z65 identifies beneficiaries with these SDOH characteristics. The SDOH flag used for this analysis was turned on if one of these Z-codes was recorded on the claim for the physician service itself (that is, the beneficiary's prior claims were not examined for additional Z-codes). Analysis of Z-codes in Medicare claims data from 2019 suggests that Z-codes are used inconsistently across provider types and population groups, and are generally underreported.[342] Therefore, we believe Z-codes do not reflect the actual rates of SDOH.

d. Behavioral Health

Beneficiaries with behavioral health diagnoses often face co-occurring physical illnesses, but often experience difficulty accessing care.[343] The combination of physical and behavioral health conditions can exacerbate both conditions and result in poorer outcomes than one condition alone.[344] Additionally, the intersection of behavioral health and health inequities is a core aspect of CMS' Behavioral Health Strategy.[345] We used the presence of one or more ICD–10–CM codes in the range of F01–F99 to identify beneficiaries with a behavioral health diagnosis.

e. Disability

Individuals under age 65 who are determined eligible for Social Security disability benefits may also be eligible for Medicare coverage.[346] Individuals may qualify for Social Security disability benefits on the basis of a medically determinable physical or mental impairment(s) that has lasted or is expected to last for a continuous period of at least 12 months or is expected to result in death.[347] Disabled beneficiaries often have complex healthcare needs and difficulty accessing care. Compared to people without disabilities, people with disabilities generally have less access to health care, have more depression and anxiety, engage more often in risky health behaviors such as smoking, and are less physically active.[348] Beneficiaries were classified as disabled for the purposes of this analysis if their original reason for qualifying for Medicare was disability; this information was obtained from Medicare's CCW enrollment data. We note that this is likely an underestimation of disability, because it does not account for beneficiaries who became disabled after becoming entitled to Medicare.

f. End-Stage Renal Disease (ESRD)

Beneficiaries with ESRD have high healthcare needs and high medical spending, and often experience comorbid conditions and poor mental health. Beneficiaries with ESRD also experience significant disparities, such as a limited life expectancy.[349] Beneficiaries were classified as ESRD for the purposes of this analysis if they were receiving Medicare ESRD coverage during the month of the discharge; this information was obtained from the CCW enrollment data.

g. Geography

Beneficiaries in some geographic areas—particularly rural areas or areas with concentrated poverty—often have difficulty accessing care. [350] [351] For this analysis, beneficiaries were classified on two dimensions: from a rural area and from an area with an area deprivation index (ADI) greater than or equal to 85.

Rural status is defined for purposes of this analysis using the primary Rural-Urban Commuting Area (RUCA) codes 4–10 (including micropolitan, small town, and rural areas) corresponding to each beneficiary's zip code. RUCA codes are defined at the census tract level based on measures of population density, urbanization, and daily commuting. The ADI is obtained from a publicly available dataset designed to capture socioeconomic disadvantage at the neighborhood level.[352] It utilizes data on income, education,

[340] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[341] *Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[342] Maksut JL, Hodge C, Van CD, Razmi, A, & Khau MT. Utilization of Z Codes for Social Determinants of Health among Medicare Fee-For-Service Beneficiaries, 2019. Office of Minority Health (OMH) Data Highlight No. 24. Centers for Medicare and Medicaid Services (CMS), Baltimore, MD, 2021. Available at *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

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[345] *https://www.cms.gov/cms-behavioral-health-strategy.*

[346] Medicare eligibility on the basis of disability is discussed in 42 CFR 406.12.

[347] *https://www.ssa.gov/disability/professionals/bluebook/general-info.htm.*

[348] *https://www.cdc.gov/ncbddd/humandevelopment/health-equity.html#ref.*

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[352] *https://www.neighborhoodatlas.medicine.wisc.edu/.*

employment, housing quality, and 13 other factors from the American Community Survey (ACS) and combines them into a single raw score, which is then used to rank neighborhoods (defined at various levels), with higher scores reflecting greater deprivation. The version of the ADI used for this analysis is at the Census Block Group level and the ADI corresponds to the Census Block Group's percentile nationally. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end of life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[353] [354] [355] [356] [357] The MedPAR discharge data was linked to the ADI data available in the CCW. Beneficiaries with no recorded ADI were treated as being from an urban area and as having an ADI less than 85.

In examining how we might expand our PFS impact analysis, we considered what framework might accurately provide insight into the relationship between PFS policies and health equity. Rather than examining changes in estimated average payments, we believe that illuminating the baseline is a necessary first step toward advancing our goal of measuring the impact of PFS policies on health equity. Table 107 displays the share of utilization for each of the health-equity relevant characteristics listed above. First, we list the share of enrollees with each characteristic. Next, we list the share of utilization by beneficiaries (that is, enrollees with at least one claim for a physician service in CY 2022) with each characteristic by provider specialty. The information contained in Table 107 is provided solely to demonstrate beneficiary utilization of services by provider specialty impact across a number of health equity dimensions and does not form the basis or rationale for the proposed policies.

In consideration of the differences between IPPS/LTCH and the PFS discussed below, we are seeking comment from interested parties about how we might structure a PFS impact analysis that addresses these and other considerations to examine how changes in the PFS would impact beneficiaries of particular groups. We are also seeking comment about how such a framework would allow us to consider developing policies that enhance health equity under our existing statutory authority. We welcome suggestions about alternative measures of health equity in our impact analysis, in particular with regard to the ADI as a proxy for disparities related to geographic variation. Finally, we seek feedback about additional categories beyond those described previously that should be considered in our analysis, along with potential data sources.

Nature of a service. In the table that details providers in terms of the beneficiaries they serve in the IPPS/LTCH PPS proposed rule, the unit of measurement we used was a hospital discharge. A discharge includes all resources involved in the hospital's caring for a beneficiary during the hospital stay. There is no parallel construct under the PFS. While the resources involved in furnishing a given discharge can and do vary under the IPPS, a discharge consists of a somewhat predictable set of resources that occur across a number of cost centers. On the other hand, a service unit under the PFS can range from very discrete services, such as a single pulse oximetry measurement (CPT code 94760) with total RVUs of 0.07 to complex services that include several visits during a global period, such as a liver transplant (CPT code 47135) with total RVUs of 160.44. As an illustration, based on the MS–DRGs reported in the claims data, the standard deviation of the mean IPPS relative weight is of similar magnitude to the mean. In contrast, based on the PFS services reported in the claims data, the standard deviation of the mean PFS RVU service is vastly larger than the mean.

TABLE 106: Differences in Claim-level Relative Weights between IPPS and PFS

	IPPS Relative Weight[358] on claim	PFS RVU on claim
Mean	1.95	2.62
Standard Deviation	1.72	1,241

In addition, under the PFS, some services furnished during a single encounter are billed in multiple units. These services could range from allergy testing (CPT codes 95004 through 95078) to anesthesia services (CPT codes 00100 through 01860). The average total RVUs for services billed in multiple units are not comparable to services billed in a single unit per encounter.

Number of practitioners serving a beneficiary and associated spending. Under the IPPS, most beneficiaries who had one or more IPPS claims during fiscal year 2022 were served by 1 or 2 providers, which accounts for most of the spending under the IPPS. The share of beneficiaries served by a given number of providers is consistent with the share of spending incurred for these discharges. Less than 10 percent of beneficiaries were served by 5 or more providers. Under the PFS, during CY

[353] 7 U.S. Department of Health & Human Services, ''Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,'' Office of the Assistant Secretary for Planning and Evaluation, March 2020. Available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-inMedicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[354] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946.*

[355] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' Annals of Internal Medicine. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available at *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671.*

[356] Cheng E, et al., ''Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' JAMA Network Open Oncology. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 (December 17, 2021), available at *https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597.*

[357] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' The Journal of Arthroplasty. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/S0883540322000493.*

[358] The IPPS relative weights are not fully comparable to PFS RVUs because IPPS payments may include outliers. Even considering outliers, however, the standard deviation on IPPS payments is only slightly higher relative to the mean ($17,104+/−$21,825).

2022, most beneficiaries with one or more PFS claims saw 5 or more practitioners. In contrast to the pattern under the IPPS, PFS spending for beneficiaries who saw 10 or more practitioners accounted for a disproportionate share of total spending. Under the IPPS, examining providers in terms of beneficiary characteristics reflects the care of most beneficiaries with one or more discharges under the IPPS. Under the PFS, the same framework would be mostly describing the forty percent of beneficiaries with one or more PFS services who account for close to 80 percent of total spending.

Utilization of services by beneficiary characteristic. As shown in Table 107, the specialty-level services utilized by beneficiaries with particular characteristics varies widely. Beneficiaries with the characteristics in Table 107 do not access services consistent with the share of enrollees with that characteristic. As a result, comparing across deciles, for example, of practitioners serving beneficiaries of one race, would often be comparing very different service mixes. How discrete a service is, the setting it is furnished in, and the associated inputs may result in services that have very different baseline allowed charges.

A significant body of literature has examined the reasons for differential access to physician services by beneficiary characteristic. Some of the explanations of the differential utilization of services include:

- Patient preferences and willingness to undergo procedures, such as due to decreased belief in treatment efficacy and concerns about surgical risks[359] [360] [361] [362]
- Geographic location: specialists and sub-specialists are sometimes clustered in urban areas due to higher demand for services [363]
- Differences in referral patterns [364] from primary care physicians and following hospitalizations
- Differences in providers who can speak the language of beneficiaries with Limited English Proficiency [365]

The information contained in Table 107 is provided solely to demonstrate beneficiary utilization by provider specialty impact across a number of health equity dimensions. This does not form the basis or rationale for the proposed policies in this proposed rule.

[359] Ibrahim SA, Siminoff LA, Burant CJ, et al. Differences in expectations of outcome mediate African American/white patient differences in ''willingness'' to consider joint replacement. *Arthritis Rheum.* 2002;46:2429–2435.

[360] Vina ER, Cloonan YK, Ibrahim SA, et al. Race, sex, and total knee replacement consideration: role of social support. *Arthritis Care Res (Hoboken)* 2013;65:1103–1111.

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[362] Hausmann LR, Mor M, Hanusa BH, et al. The effect of patient race on total joint replacement recommendations and utilization in the orthopedic setting. *J Gen Intern Med.* 2010;25:982–988.

[363] Cyr, M.E., Etchin, A.G., Guthrie, B.J. et al. Access to specialty healthcare in urban versus rural US populations: a systematic literature review. BMC Health Serv Res 19, 974 (2019). *https://doi.org/10.1186/s12913-019-4815-5.*

[364] Landon BE, Onnela J, Meneades L, O'Malley AJ, Keating NL. Assessment of Racial Disparities in Primary Care Physician Specialty Referrals. JAMA Netw Open. 2021;4(1):e2029238. doi:10.1001/jamanetworkopen.2020.29238.

[365] Berdahl TA, Kirby JB. Patient-Provider Communication Disparities by Limited English Proficiency (LEP): Trends from the US Medical Expenditure Panel Survey, 2006–2015. J Gen Intern Med. 2019 Aug;34(8):1434–1440. doi: 10.1007/s11606–018–4757–3. Epub 2018 Dec 3. PMID: 30511285; PMCID: PMC6667581.

TABLE 107: Beneficiary Service Utilization by Payment Impact Specialty Across Demographic and Equity Characteristics, CY 2022

	All	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
	Total # of Enrollees	% Enrollees													
All Enrollees	28,285,281	79.8 %	7.4 %	5.8 %	3.2 %	0.5 %	0.9 %	31.5 %	0.9 %	7.7 %	17.7 %	16.6 %	18.0 %	22.6 %	18.6 %
	Total Services	% Services													
All Users	2,504,984,961	81.8 %	7.2 %	5.1 %	2.4 %	0.4 %	0.0 %	3.7 %	1.9 %	6.7 %	18.8 %	17.7 %	19.0 %	16.3 %	23.7 %
ALLERGY/IMMUNOLOGY	20,089,081	84.0 %	5.5 %	4.1 %	2.5 %	0.1 %	0.0 %	0.5 %	0.3 %	4.4 %	8.6 %	7.8 %	8.6 %	11.7 %	16.3 %
ANESTHESIOLOGY	9,563,100	82.9 %	6.4 %	5.4 %	2.1 %	0.5 %	0.0 %	6.2 %	1.2 %	6.9 %	19.5 %	17.7 %	19.6 %	16.8 %	30.7 %
CARDIAC SURGERY	457,226	82.7 %	5.9 %	5.8 %	2.1 %	0.5 %	0.0 %	2.1 %	4.3 %	8.0 %	16.6 %	15.5 %	16.8 %	22.7 %	16.7 %
CARDIOLOGY	71,347,515	81.5 %	7.2 %	5.3 %	2.8 %	0.3 %	0.0 %	1.8 %	2.4 %	7.3 %	15.8 %	14.6 %	15.9 %	17.4 %	16.4 %
COLON AND RECTAL SURGERY	724,904	83.7 %	5.6 %	4.7 %	2.5 %	0.2 %	0.0 %	0.7 %	1.3 %	5.7 %	13.6 %	12.6 %	13.8 %	12.8 %	19.9 %

[366] American Asian and Pacific Islander .
[367] American Indian and Alaskan Native.

	All	Total # of Enrollees	% Enrollees												
			White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Eyer	Dual Eyer	LIS/Dual Eyer	Non-Metro	Disability
CRITICAL CARE	1,867,947		76.1 %	10.3 %	6.9 %	3.4 %	0.4 %	0.1 %	5.3 %	5.2 %	7.4 %	28.8 %	27.6 %	29.2 %	13.0 %	27.1 %
DERMATOLOGY	49,298,654		93.2 %	0.9 %	1.6 %	0.7 %	0.1 %	0.0 %	0.6 %	0.5 %	3.7 %	4.2 %	3.8 %	4.3 %	15.4 %	7.4 %
EMERGENCY MEDICINE	21,952,901		78.7 %	9.6 %	6.0 %	2.4 %	0.6 %	0.2 %	5.3 %	3.1 %	7.8 %	25.1 %	23.8 %	25.4 %	17.3 %	24.8 %
ENDOCRINOLOGY	13,439,562		82.9 %	5.2 %	4.2 %	3.7 %	0.2 %	0.0 %	1.1 %	1.4 %	4.2 %	11.2 %	10.2 %	11.3 %	9.1 %	16.4 %
FAMILY PRACTICE	99,140,616		84.0 %	5.8 %	4.3 %	2.3 %	0.5 %	0.2 %	11.6 %	0.9 %	8.0 %	16.3 %	15.1 %	16.5 %	22.0 %	19.4 %
GASTROENTEROLOGY	25,248,189		84.4 %	5.7 %	4.0 %	2.0 %	0.2 %	0.0 %	0.6 %	1.1 %	5.3 %	11.2 %	10.4 %	11.3 %	12.9 %	17.9 %
GENERAL PRACTICE	5,342,814		73.9 %	8.4 %	9.8 %	3.9 %	0.5 %	0.1 %	12.5 %	1.3 %	7.2 %	28.6 %	27.6 %	28.8 %	16.5 %	23.2 %
GENERAL SURGERY	9,166,757		80.9 %	8.2 %	5.8 %	1.9 %	0.5 %	0.0 %	3.7 %	5.2 %	8.8 %	23.0 %	21.9 %	23.3 %	21.9 %	28.9 %
GERIATRICS	1,625,353		76.7 %	9.3 %	5.8 %	5.1 %	0.4 %	0.6 %	30.1 %	1.6 %	5.1 %	30.8 %	30.2 %	31.3 %	9.1 %	17.2 %
HAND SURGERY	3,013,821		87.6 %	3.7 %	3.0 %	1.7 %	0.2 %	0.0 %	0.1 %	0.5 %	3.8 %	7.4 %	6.7 %	7.5 %	11.4 %	13.2 %

	All	Total # of Enrollees	% Enrollees												
			White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Eyer	Dual Eyer	LIS/Dual Eyer	Non-Metro	Disability
HEMATOLOGY/ONCOLOGY	458,304,885		81.4 %	8.1 %	4.8 %	2.4 %	0.3 %	0.0 %	1.0 %	1.2 %	7.4 %	13.9 %	12.9 %	14.0 %	14.5 %	18.2 %
INFECTIOUS DISEASE	48,318,745		86.6 %	4.9 %	4.2 %	1.1 %	0.2 %	0.0 %	0.4 %	3.3 %	6.7 %	12.8 %	11.4 %	12.9 %	5.4 %	24.5 %
INTERNAL MEDICINE	142,667,884		80.0 %	8.2 %	5.2 %	3.3 %	0.4 %	0.1 %	10.0 %	2.4 %	6.6 %	19.9 %	18.9 %	20.1 %	15.1 %	21.0 %
INTERVENTIONAL PAIN MGMT	15,783,928		83.7 %	6.3 %	5.4 %	1.7 %	0.4 %	0.0 %	3.7 %	0.6 %	7.2 %	18.3 %	16.5 %	18.4 %	15.3 %	32.5 %
INTERVENTIONAL RADIOLOGY	6,371,060		75.5 %	10.3 %	7.1 %	3.6 %	0.3 %	0.0 %	0.6 %	11.3 %	7.0 %	21.3 %	20.1 %	21.5 %	14.6 %	20.5 %
MULTISPECIALTY CLINIC/OTHER PHYS	1,874,372		81.5 %	6.6 %	4.6 %	3.2 %	0.7 %	0.2 %	6.7 %	1.9 %	5.9 %	19.3 %	18.3 %	19.4 %	15.8 %	20.7 %
NEPHROLOGY	15,193,786		61.7 %	19.2 %	10.8 %	4.7 %	0.8 %	0.0 %	1.5 %	35.1 %	10.2 %	31.4 %	29.3 %	31.8 %	14.4 %	26.1 %
NEUROLOGY	49,770,374		83.8 %	5.6 %	5.0 %	2.0 %	0.3 %	0.0 %	4.2 %	0.7 %	5.3 %	20.4 %	19.2 %	20.6 %	12.9 %	40.7 %
NEUROSURGERY	2,430,012		83.7 %	6.3 %	4.3 %	2.0 %	0.4 %	0.0 %	1.0 %	0.9 %	8.1 %	17.0 %	15.8 %	17.2 %	20.6 %	25.8 %
NUCLEAR MEDICINE	1,840,191		82.2 %	6.1 %	5.4 %	2.6 %	0.1 %	0.0 %	0.6 %	1.0 %	6.0 %	14.6 %	13.7 %	14.7 %	9.0 %	15.4 %

	All	% Enrollees														
	Total # of Enrollees	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
OBSTETRICS/GYNECOLOGY	11,867,340	81.2 %	8.6 %	4.6 %	2.2 %	0.5 %	0.0 %	1.1 %	0.6 %	6.8 %	14.2 %	13.4 %	14.3 %	15.7 %	18.3 %
OPHTHALMOLOGY	55,861,861	83.3 %	5.2 %	4.7 %	3.5 %	0.3 %	0.0 %	0.1 %	1.4 %	5.6 %	10.9 %	10.0 %	11.0 %	17.4 %	9.8 %
ORTHOPEDIC SURGERY	48,700,496	85.2 %	5.4 %	4.0 %	2.1 %	0.3 %	0.0 %	0.3 %	0.5 %	6.0 %	9.7 %	8.7 %	9.7 %	17.4 %	13.8 %
OTOLARYNGOLOGY	13,168,571	84.1 %	5.8 %	4.2 %	2.4 %	0.2 %	0.0 %	0.8 %	0.5 %	5.7 %	11.8 %	10.9 %	11.8 %	16.9 %	16.0 %
PATHOLOGY	22,251,357	83.3 %	6.1 %	4.3 %	2.4 %	0.3 %	0.0 %	0.5 %	2.1 %	6.2 %	13.2 %	12.2 %	13.3 %	18.1 %	15.6 %
PEDIATRICS	2,097,101	78.4 %	7.1 %	8.9 %	1.4 %	0.3 %	0.1 %	3.9 %	1.9 %	9.4 %	19.3 %	18.2 %	19.4 %	12.4 %	29.8 %
PHYSICAL MEDICINE	24,542,987	80.2 %	8.2 %	4.9 %	3.0 %	0.3 %	0.0 %	3.8 %	1.2 %	5.6 %	26.4 %	25.3 %	26.7 %	13.7 %	34.7 %
PLASTIC SURGERY	1,800,630	84.2 %	6.4 %	4.6 %	1.4 %	0.4 %	0.0 %	2.0 %	1.6 %	5.4 %	17.9 %	17.0 %	18.0 %	16.2 %	20.0 %
PSYCHIATRY	9,308,283	75.7 %	10.6 %	6.7 %	2.5 %	0.5 %	1.0 %	94.6 %	0.7 %	7.6 %	51.8 %	50.0 %	52.2 %	12.7 %	58.7 %
PULMONARY DISEASE	13,466,574	81.7 %	7.8 %	5.0 %	2.3 %	0.3 %	0.1 %	5.0 %	2.4 %	7.3 %	19.3 %	18.1 %	19.5 %	17.2 %	23.2 %

	All	% Enrollees																
	Total # of Enrollees	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	12,793,376	83.3 %	6.4 %	4.7 %	2.0 %	0.4 %	0.0 %	0.9 %	0.9 %	7.1 %	11.5 %	10.5 %	11.6 %	20.1 %	13.4 %
RADIOLOGY	181,430,147	81.4 %	6.7 %	5.3 %	2.8 %	0.3 %	0.0 %	0.4 %	1.4 %	5.3 %	15.0 %	14.0 %	15.1 %	14.3 %	17.6 %
RHEUMATOLOGY	166,143,825	85.0 %	5.4 %	4.7 %	1.9 %	0.2 %	0.0 %	0.4 %	0.4 %	5.7 %	6.5 %	5.5 %	6.6 %	12.9 %	21.3 %
THORACIC SURGERY	729,721	80.8 %	8.5 %	5.1 %	2.2 %	0.4 %	0.0 %	2.5 %	4.3 %	8.0 %	18.7 %	17.5 %	19.0 %	19.9 %	19.2 %
UROLOGY	54,057,785	83.2 %	7.4 %	3.9 %	1.5 %	0.2 %	0.0 %	0.4 %	0.7 %	5.4 %	8.3 %	7.6 %	8.4 %	14.0 %	15.9 %
VASCULAR SURGERY	5,409,525	74.5 %	12.9 %	7.0 %	2.3 %	0.3 %	0.0 %	1.2 %	16.2 %	8.0 %	23.2 %	21.6 %	23.4 %	15.1 %	22.1 %
AUDIOLOGIST	2,055,569	85.3 %	4.3 %	3.9 %	2.6 %	0.3 %	0.1 %	0.2 %	0.6 %	4.5 %	12.1 %	11.5 %	12.2 %	15.4 %	12.4 %
CHIROPRACTOR	17,158,259	91.2 %	2.0 %	2.1 %	1.2 %	0.3 %	0.0 %	0.0 %	0.3 %	5.9 %	7.5 %	6.7 %	7.6 %	27.2 %	12.5 %
CLINICAL PSYCHOLOGIST	6,463,428	83.1 %	6.4 %	4.8 %	1.8 %	0.3 %	1.0 %	88.4 %	0.9 %	4.3 %	32.2 %	31.2 %	32.5 %	10.7 %	36.2 %
CLINICAL SOCIAL WORKER	6,599,714	82.9 %	8.3 %	3.9 %	1.0 %	0.4 %	1.6 %	99.6 %	0.8 %	6.7 %	43.9 %	42.5 %	44.3 %	14.7 %	49.2 %

	All	Total # of Enrollees	% Enrollees											
			White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Ever	Dual Ever	LIS/Dual Ever	Non-Metro	Disability
DIAGNOSTIC TESTING FACILITY	23,489,346		83.1 %	6.2 %	4.5 %	2.8 %	0.2 %	0.0 %	0.3 %	0.6 %	5.4 %	12.3 %	11.1 %	12.4 %	14.0 %	16.3 %
INDEPENDENT LABORATORY	31,744,057		78.1 %	12.5 %	5.6 %	1.6 %	0.2 %	0.0 %	2.4 %	1.6 %	9.7 %	39.8 %	39.3 %	40.3 %	14.7 %	26.4 %
NURSE ANES / ANES ASST	543,164		86.1 %	4.3 %	4.8 %	1.3 %	0.7 %	0.0 %	14.2 %	1.6 %	8.3 %	16.9 %	15.6 %	17.1 %	31.4 %	23.8 %
NURSE PRACTITIONER	128,768,200		84.8 %	7.2 %	3.7 %	1.4 %	0.4 %	0.1 %	10.6 %	1.9 %	8.5 %	21.1 %	20.2 %	21.5 %	22.1 %	25.7 %
OPTOMETRY	19,912,703		87.0 %	5.1 %	2.8 %	1.6 %	0.5 %	0.0 %	0.1 %	0.6 %	8.8 %	11.7 %	10.8 %	11.8 %	33.8 %	12.1 %
ORAL/MAXILLOFACIAL SURGERY	296,908		79.2 %	4.5 %	6.0 %	6.0 %	0.1 %	0.0 %	1.2 %	0.5 %	3.6 %	20.8 %	19.9 %	20.9 %	10.6 %	20.4 %
PHYSICAL/OCCUPATIONAL THERAPY	159,690,345		85.1 %	4.7 %	3.8 %	2.7 %	0.2 %	0.0 %	2.3 %	0.5 %	3.7 %	10.8 %	10.2 %	10.9 %	13.5 %	13.0 %
PHYSICIAN ASSISTANT	65,080,844		86.5 %	5.1 %	3.5 %	1.4 %	0.5 %	0.1 %	4.3 %	1.1 %	6.0 %	13.7 %	12.8 %	13.9 %	20.2 %	18.6 %
PODIATRY	27,252,983		80.8 %	8.7 %	5.5 %	2.1 %	0.4 %	0.0 %	0.4 %	2.3 %	6.4 %	23.9 %	23.0 %	24.2 %	14.9 %	20.9 %
PORTABLE X-RAY SUPPLIER	3,380,767		79.2 %	10.4 %	6.5 %	2.2 %	0.3 %	0.2 %	0.2 %	2.1 %	9.9 %	59.1 %	59.3 %	60.0 %	17.2 %	28.5 %

		All	White	Black	Hispanic	AAPI[366]	AIAN[367]	SDOH	Behavioral Health	ESRD	ADI	LIS Eyer	Dual Eyer	LIS/Dual Eyer	Non-Metro	Disability
	Total # of Enrollees	% Enrollees														
OTHER	311,487,534		74.2 %	10.1 %	8.6 %	3.2 %	1.0 %	0.0 %	2.1 %	3.8 %	8.2 %	44.9 %	42.9 %	45.2 %	20.7 %	52.9 %
D6	2,597,888		47.5 %	21.5 %	10.2 %	0.1 %	0.0 %	0.0 %	0.0 %	15.5 %	17.0 %	65.5 %	64.6 %	65.5 %	12.1 %	67.8 %

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D. Impact of Proposed Changes Related to Telehealth Services

We are proposing to implement the provisions of the CAA, 2023 that amended section 1834(m) of the Act) to extend the application of certain Medicare telehealth flexibilities through December 31, 2024, including allowing Medicare telehealth services to be furnished to patients located anywhere within the U.S.; continuing the expanded scope of telehealth practitioners to include occupational therapists, physical therapists, speech-language pathologists, and audiologists; extending payment for telehealth services furnished by FQHCs and RHCs; and delaying the requirement that there be an in-person visit with the physician or practitioner within 6 months before an initial mental health telehealth service.

In this proposed rule, we are proposing a refined process for considering requests received for addition of services to the Medicare Telehealth Services List, which would include a decision on whether the services should be proposed for inclusion on the list on either a permanent or provisional basis. Because the underlying criteria for adding services to the Medicare Telehealth Services List are not changing, we do not expect this proposal to have an impact on the utilization of Medicare Telehealth services beginning in CY 2024 but we will continue to monitor utilization of these services. We are proposing that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) would be paid at the non-facility PFS rate. Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the PFS facility rate. As we are currently paying for the majority of services that will be billed with POS 10 at the PFS non-facility rate under the PHE-specific policy of paying the place of service code had the service been furnished in person, we believe that these services furnished via telehealth will largely be paid as they are currently. Therefore, we believe the impact of this proposal will roughly neutral even if utilization remains at current levels for these services. We anticipate that these provisions will result in continued utilization of Medicare telehealth services during CY 2024 at levels comparable to observed utilization of these services during the PHE for COVID–19.

E. Other Provisions of the Regulation

1. Impact of Proposals for Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In section II.K.2. of this proposed rule, we are: (1) proposing to allow payment for dental examinations, diagnostic, and treatment services prior to and during certain treatments for cancer (chemotherapy and CAR–T cell therapy); (2) proposing to allow payment for dental examinations, diagnostic, and treatment services prior to and during antiresorptive and/or antiangiogenic drug therapy associated with the treatment for cancer; and (3) requesting comments on other types of cardiovascular interventions (analogous to cardiac valve replacements and valvuloplasty procedures) where dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other cardiovascular covered medical services.

If we were to finalize the proposal that Medicare Part A and Part B payment can be made for oral or dental examination, and necessary treatment, performed prior to and during certain cancer treatments or drug therapies associated with managing cancer related care, we do not anticipate any significant increase in utilization or payment impact for additional dental services given the historically low utilization of these therapies. Although, we acknowledge that the observed utilization of these services might have been low because of the size of the population of patients whose treatment would include such dental services and also because the dental services have been viewed as subject to the payment preclusion under section 1862(a)(12).

Based on an analysis of 2018–2022 incurred claims experience, we estimate that there are potentially 155,000 additional beneficiaries who might receive dental services for which Medicare payment could be made, relative to the current number of beneficiaries that received dental services. These are beneficiaries who would receive any of the treatments identified in our proposals for CY 2024 (that is, chemotherapy/CAR T/bone-modifying agent therapies used in the treatment of cancer) who would likely require dental services, and could utilize dental services for which services Medicare could pay in CY 2024, if these proposals are finalized. The estimated average cost for these additional dental services is about $525 per person. This assumption is based on an analysis of 2019 incurred claims, but we believe results using more recent data would not be likely to change, due to the limited claims involving these services. Based on this same analysis, the effective rate of coverage was less than 0.2 percent. We do acknowledge that the actual take-up rate of services could be higher due to the proposed additional examples of medical services to which dental services are inextricably linked, which may raise awareness that payment is available. Therefore, we prepared impact estimates under the utilization assumptions of 0.2 percent and between 1–3 percent. We then applied these utilization ratios to estimate projected payments for dental exams and treatments in connection with cancer therapies. We found that the estimated yearly impact beginning in CY 2024 to be roughly $162,000 per year with a 0.2 percent utilization assumption, and roughly $800,000 to 2 million per year for the utilization assumptions of 1–3 percent. Therefore, we do not anticipate a significant payment impact for these provisions. We note, however, that if we were to finalize, as discussed in section II.K. of this proposed rule, payment in other clinical scenarios for dental services inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, we may adjust this estimate for the final rule.

We continue to believe that because we are updating existing Medicare payment policies by proposing additional examples of clinical scenarios where dental services are inextricably linked to covered medical services, as stated in the CY 2023 PFS final rule, it is not appropriate to incorporate these budget neutrality adjustments into the conversion factor. Additionally, while the impact of access to these services to some individuals enrolled in Medicare could be very significant, we do not anticipate a significant impact in the context of overall spending and utilization under the PFS nor do we anticipate significant utilization and spending impact of these policies finalized in section II.K.2. of this proposed rule.

We acknowledge that the actual take-up rate of services could be higher than the utilization assumptions included within our current estimates. We continue to be open to updating and conducting further impact analysis once we have additional data and input from interested parties.

2. Impact of Proposal To Implement Separate Payment for the Office/Outpatient (O/O) E/M Visit Inherent Complexity Add-on Code (HCPCS G2211)

In recent years, the AMA's CPT Editorial Committee has restructured the E/M visit code sets largely to acknowledge changes in medical practice. The AMA RUC has reviewed and provided us recommendations for the revised E/M visit code sets in the context of the generally recognized need to better recognize resources involved in furnishing different types of services within the broader PFS. While we adopted the RUC-recommended values for the O/O E/M visit code family in the CY 2021 final rule, recognizing that those values generally reflect the resources involved in furnishing those services, we did not believe those valuations appropriately reflected the resource costs involved in furnishing primary and other similarly longitudinal medical care for a serious or complex condition in office settings. To address this concern, effective beginning in CY 2021, we finalized an add-on code to separately pay for visit complexity inherent to O/O E/M visits for primary care and other medical care services that are part of ongoing care related to a patient's single, serious, or complex condition in the office setting (the O/O E/M visit inherent complexity add-on). After we finalized the CY 2021 payment changes for O/O E/M visits, in the CAA of 2021, Congress imposed a statutory moratorium on Medicare payment for the O/O E/M visit inherent complexity add-on code until January 1, 2024.

We propose to implement payment for the O/O E/M visit inherent complexity add-on, HCPCS code G2211, with significant refinements to target improved payment for primary and other similar longitudinal care for serious or complex conditions. Specifically, we are proposing that the O/O E/M visit complexity add-on code cannot be billed with visits reported using Modifier 25 which is used to indicate that the service is billed on the same day as a minor procedure or another E/M visit. (Previously, in the CY 2021 final rule, we stated we would not expect such billing; but as there was no explicit prohibition, these visits were included in the budget neutrality adjustment (85 FR 84572)). We also propose to set PFS rates with a refined, more specific utilization assumption that better recognizes likely uptake of the code, differential use among specialties, and new and established patient visits, among other changes. These refined assumptions were developed, taking into consideration perspectives and information provided by interested parties. The resulting estimate reflects that the O/O E/M visit inherent complexity add-on code would likely be reported with approximately 38 percent of all O/O E/M visits for CY 2024. As discussed previously and shown below, we estimate the specific portion of the total budget neutrality adjustment attributable to the proposal to make payment for the O/O E/M inherent complexity add-on code to be approximately 2.00 percent compared to an attributable budget neutrality adjustment of 3.20 percent as calculated in CY 2021 rulemaking.

3. Advancing Access to Behavioral Health

a. Impact of Proposed Payment for Marriage and Family Therapist (MFT) Services and Mental Health Counselor (MHC) Services

As discussed in section II.J. of this proposed rule, section 4121 of CAA, 2023 added section 1861(s)(2)(II) to establish a new Medicare benefit category for MFT services and MHC services furnished and billed by MFTs and MHCs, respectively. MFT and MHC services are defined in section 1861(lll)(2) and 1861(lll)(4), respectively, as services for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital). An MFT or MHC is defined as an individual who possesses a master's or doctor's degree, is licensed or certified by the State in which they furnish services, who has performed at least 2 years of clinical supervised experience, and meets other requirements as the Secretary determines appropriate. Section 1833(a)(1)(FF) of the statute requires that MFT and MHC services be paid at 75 percent of the amount determined for payment of a clinical psychologist. MFT and MHC services are excluded from consolidated billing requirements under the skilled nursing facility prospective payment system. Services furnished by an MFT and MHC are covered when furnished in a rural health clinic and federally qualified health center. In addition, the hospice interdisciplinary team is required to include at least one social worker, MFT or MHC. Expenditures associated with payment for services furnished by MFTs and MHCs in CY 2024 will be incorporated into budget neutrality for PFS ratesetting in future years.

4. Drugs and Biological Products Paid Under Medicare Part B

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023 final rule, we finalized several policies to implement the provision, including: reporting requirements for the JW and JZ modifiers; the date upon which we will begin to edit claims for appropriate use of the JW and JZ modifiers, October 1, 2023; the definition of ''refundable single-dose container or single-use package drug''; the manner in which refund amounts will be calculated; the annual basis we will send reports to manufacturers; the dispute resolution process; and enforcement provisions. In section III.A of this proposed rule, we are proposing the date of the initial report to manufacturers, the date for subsequent reports, method of calculation when there are multiple manufacturers for a refundable drug, increased applicable percentages for drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug.

For this proposed rule, we reanalyzed JW modifier data from 2021 as if the data represented dates of service on or after the effective date of section 90004 of the Infrastructure Act (that is, January 1, 2023).[368] That is, to assess if there was a change in the status of the billing and payment codes that were identified in the proposed rule as met the definition of refundable single-dose container or single-use package drug and have 10 percent or more discarded units, except for five drugs with higher applicable percentages finalized in the CY 2023 final rule or as proposed under this proposed rule.

Overall in the 2021 calendar year, Medicare paid nearly $1.56 billion for discarded amounts of drugs from a

[368] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

single-dose container or single-use package paid under Part B. In that year, there were 51 billing and payment codes with 10 percent or more discarded units based on JW modifier data. Of these, 11 did not meet the definition of refundable single-dose container or single-use package drug in section 1847A(h)(8) of the Act because they are multiple source drug codes; 5 were excluded from the definition of refundable single-dose container or single-use package drug (as specified in section 1847A(h)(8)(B) of the Act) because they are identified as radiopharmaceuticals or imaging agents in FDA-approved labeling; and 3 are products referred to as skin substitutes, which were removed because we anticipate making changes to coding and payment policies regarding those products in future rulemaking. After these exclusions, there were 31 billing and payment codes that met the definition of refundable single-dose container or single-use package drug and have discarded units above the relevant finalized applicable percentage. Of these, three have discarded units that would fall below increased applicable percentages proposed in this proposed rule.

We estimated refund amounts as described in section 1847A(h)(3) of the Act were calculated based on this data by subtracting the percent units discarded by 10 percent (the applicable percentage), except for drugs with higher applicable percentages finalized in the CY 2023 final rule or as proposed under this proposed rule. Then, we multiplied the appropriate percentage by the CY 2021 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. Based on this data, there would be approximately $83.1 million in refunds due from manufacturers for the calendar year of 2021 ($20.8 million each calendar quarter). See Table 108.

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TABLE 108: Estimated Refund Amounts Based on CY 2021 JW Modifier Data[369]

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
Q9965	$2,276,001.01	67.41%	Y; Radiopharm or imaging agent	10%			
J7342	$4,559.95	53.26%	N	10%	43.26%	$1,972.63	$493.16
J9281	$26,703,749.86	37.60%	N	35%	2.60%	$694,297.50	$173,574.37
J9262	$220,987.21	30.98%	N	26% (proposed)	4.98%	$11,005.16	$2,751.29
J9043	$146,745,385.39	29.11%	N	10%	19.11%	$28,043,043.15	$7,010,760.79
J9041	$380,429,509.43	27.00%	Y; multiple source	10%			
J9351	$475,677.64	26.37%	Y; multiple source	10%			
Q9961	$19,366.66	26.28%	Y; Radiopharm or imaging agent	10%			
J0894	$17,872,985.28	24.16%	Y; multiple source	10%			
J9044	$4,616,507.83	21.91%	N; see new single source codes J9046, J9048, J9049	10%	11.91%	$549,826.08	$137,456.52
J9025	$37,997,710.06	21.83%	Y; multiple source	10%			
J9017	$1,733,222.58	21.25%	Y; multiple source	10%			
J1448	$1,739,523.98	20.85%	N	10%	10.85%	$188,738.35	$47,184.59
J0775	$68,490,974.85	20.83%	N	45% proposed			
J9065	$451,404.96	20.26%	Y; multiple source	10%			
J9223	$90,785,710.74	20.25%	N	10%	10.25%	$9,305,535.35	$2,326,383.84
J0565	$3,928,811.98	19.53%	N	10%	9.53%	$374,415.78	$93,603.95

[369] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
J9178	$9,922.54	18.95%	Y; multiple source	10%			
J9229	$17,911,595.08	18.21%	N	10%	8.21%	$1,470,541.96	$367,635.49
J0223	$10,731,531.69	17.00%	N	26% (proposed)			
Q9966	$2,230,516.82	16.89%	Y; Radiopharm or imaging agent	10%			
J1640	$8,405,837.59	15.52%	Y; filtered	10%			
J9153	$5,526,153.53	15.00%	N	10%	5.00%	$276,307.68	$69,076.92
J2425	$124,548.01	14.07%	N	10%	4.07%	$5,069.10	$1,267.28
J9027	$62,602.70	13.98%	Y; multiple source	10%			
J9264	$347,464,875.59	13.86%	N	10%	3.86%	$13,412,144.20	$3,353,036.05
J2796	$257,348,654.37	13.60%	N	10%	3.60%	$9,264,551.56	$2,316,137.89
Q9956	$737,908.86	13.03%	Y; Radiopharm or imaging agent	10%			
J0515	$16,911.88	12.88%	Y; multiple source	10%			
J2562	$18,752,340.26	12.81%	N	10%	2.81%	$526,940.76	$131,735.19
J9179	$43,581,966.38	12.71%	N	10%	2.71%	$1,181,071.29	$295,267.82
J9307	$22,805,063.36	12.65%	N	10%	2.65%	$604,334.18	$151,083.54
J9037	$33,082,159.80	12.10%	N	10%	2.10%	$694,725.36	$173,681.34
J3396	$2,537,428.32	11.93%	N	10%	1.93%	$48,972.37	$12,243.09
J9042	$169,482,924.33	11.89%	N	10%	1.89%	$3,203,227.27	$800,806.82
J9319	$6,572,808.69	11.78%	Y; multiple source	10%			
Q9950	$516,142.11	11.77%	Y; Radiopharm or imaging agent	10%			
J0485	$76,861,131.89	11.61%	N	10%	1.61%	$1,237,464.22	$309,366.06
J9205	$59,413,621.44	11.55%	N	10%	1.55%	$920,911.13	$230,227.78

HCPCS Code	2021 Total Medicare Allowed Amount	Percent Units Discarded	Excluded (Y/N)	Applicable percentage	% Exceeding applicable percentage	Estimated annual refund	Estimated quarterly refund
J9228	$417,946,062.94	11.40%	N	10%	1.40%	$5,851,244.88	$1,462,811.22
J3241	$306,975,463.35	11.32%	N	10%	1.32%	$4,052,076.12	$1,013,019.03
J2997	$66,254,826.34	11.31%	N	10%	1.31%	$867,938.23	$216,984.56
J3300	$8,964,090.01	10.97%	N	90% proposed			
J0122	$144,528.76	10.84%	N	10%	0.84%	$1,214.04	$303.51
J3101	$12,921,647.56	10.67%	N	10%	0.67%	$86,575.04	$21,643.76
J9315	$23,154,637.13	10.33%	Y; multiple source	10%			
J9269	$7,755,186.19	10.15%	N	26% proposed			
J9352	$9,225,195.63	10.10%	N	10%	0.10%	$9,225.20	$2,306.30
Q4121	$6,484,123.19	17.85%	Y; skin substitute (proposed)	10%	7.85%		
Q4106	$1,511,046.28	16.64%	Y; skin substitute (proposed)	10%	6.64%		
Q4101	$2,176,035.02	14.58%	Y; skin substitute (proposed)	10%	4.58%		
				TOTAL		$82,883,368.59	$20,720,842.15

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There are several limitations to this analysis that could substantially affect the total quarterly refund. Since new drugs are continually being approved,

this estimate does not consider newer drugs that will meet the definition of refundable single-dose container or single-use package drug on or after the effective date of January 1, 2023. Since section 1847A(h)(8)(B)(iii) of the Act excludes drugs approved by FDA on or after November 15, 2021 and for which payment has been made under Part B for fewer than 18 months from this definition, we expect an impact on refund amounts after the 18-month exclusion has ended if the drug otherwise meets the definition. We also note that this estimate is based on CY 2021 data for discarded drug amounts, which, for reasons discussed in the CY 2023 final rule (87 FR 69716), we believe to be an underestimate due to the frequent omission of the JW modifier. Once we begin to edit claims for both the JW and JZ modifiers, reported discarded drug amounts will likely increase. Other substantial changes to this estimate may occur if a billing and payment code no longer meets this definition. For example, if a generic version of one of these drugs is marketed, the billing and payment code will become a multiple source drug code and will no longer meet the definition of refundable single-dose container or single-use package drug. Subsequently, the manufacturers will not be responsible for refunds under this provision. There may be changes in the percent discarded units for a given refundable single-dose container or single-use package drug if the manufacturer introduces additional vial sizes or modifies the vial size to reduce the amount discarded. Lastly, since data from the CMS website only includes billing and payment codes on the ASP drug pricing file [370] and implementation of section 90004 of the Infrastructure Act is not restricted to billing and payment codes included on the file, there may be other applicable data that was not assessed as part of this estimate.

a. Impacts Related to the Issuance of the Initial Report

In section III.A.3.b. of this proposed rule, we propose to issue the initial refund report to manufacturers, to include all calendar quarters for 2023, no later than December 31, 2024. Accordingly, as discussed in section III.A.3.c., we propose to require that the refund amounts specified in the initial refund report be paid no later than February 28, 2025, except in circumstances where a report is under dispute.

[370] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

Delaying the receipt of the rebate, that is in 2025 instead of 2024, only represents a cost to the extent the SMI trust fund receives less interest revenue. Only a portion of SMI trust fund revenue ends up invested in the bond portfolio. Based on current SMI trust fund operation patterns a delay in rebate collection as described in the rule would represent a cost less than $2 million dollars in any given year and therefore would be negligible to SMI trust fund operations.

b. Impacts Related to the Application for Consideration

As described in section VII.B.1. of this proposed rule, the information collection requirements, we estimate the annual burden per applicant to be 5 hours. If we anticipate no more than 25 applications per year, the total annual drafting and submitting burden would be 125 hours (25 applications per year × 5 hours per applicant). We estimate an annual cost of this burden to be $4,937.50 ($39.50/hour × 125 hours).

5. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this proposed rule, we are proposing to include Remote Patient Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) services, and the proposed Community Health Integration (CHI) and Principal Illness Navigation (PIN) services if finalized, in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. Due to the growing number of services in the code, we are also proposing to revise the calculation for G0511 to include the weighted average of these services based on utilization under the PFS as this may provide a more complete and accurate payment amount.

In terms of estimated impacts to the Medicare program, expanding use of General Care Management HCPCS code G0511 to include RPM, RTM, CHI, and PIN may result in an increase in spending. Prior updates to G0511 have resulted in negligible increases.

6. RHC and FQHC CfC Changes: Permitting MFTs and MHCs To Furnish Services

Section 4121 of the CAA, 2023 amends section 1861(aa)(1)(B) of the Act by adding MFTs and MHCs as eligible practitioners of RHCs and FQHCs beginning January 1, 2024. We are proposing regulation text changes to permit MFT and MHCs to provide services furnished at RHCs and FQHCs. These changes would include MFTs and MHCs as members of the staff who may be the owner or an employee of the clinic or center, or furnish services under contract to the clinic or center. Along with other permitted physicians and nonphysician practitioners, MFT and MHCs may be available to furnish patient care services at all times the clinic or center operates.

At § 491.9(b)(3) RHCs and FQHCs must have patient care policies that include: (1) a description of the services the clinic or center furnishes directly or through agreement or arrangement; (2) guidelines for medical management of health problems; and (3) rules for storage, handling, and administration of drugs and biologicals. Additionally, § 491.9(b)(4) states that the RHC and FQHC patient policies must regularly be reviewed at least once every 2 years by a group of professional personnel that includes one or more physicians, one or more physician assistants (PAs) or nurse practitioners (NPs), and at least one person who is not a member of the clinic or center staff. If an RHC or FQHC provides services furnished by an MHC or MFT they must update their patient care policies with a description of the services they will provide.

The most recently published collection of information for RHCs and FQHCs (OMB control number 0938–0334), estimates that an annual review of the patient care policies may take approximately 2 hours. Therefore, we assume, it would take each medical professional (at least one physician and at least one PA or NP) 1 hour to review all policies and procedures, annually. Based on the prior analysis, we estimate it will take 15 minutes to add the description of MFT and MHC services. We also assume that only half of the RHCs and half of the FQHCs would have this burden applied to them, for a total burden estimate of $361,891.05. We note that there would be variations in how many clinics or centers employ or contract with an MFT and MHC based on their ability to expand their services. We also recognize that some RHCs and FQHCs may already provide these services as some States provide reimbursement under the Medicaid program; however, we do not know the exact number of clinics or centers that already have these practitioners on staff and would not incur the burden.

While this proposed rule does have a 1-time burden, there is evidence to suggest there are long-term financial savings in integrating mental health in medical care. Effectively integrating mental and medical care can save upwards of $52 billion annually due to the existing Medicare mental health

coverage gap.[371] Though this total encompasses all facility types, expanding access to MFT and MHC services in RHCs and FQHCs will have individual and societal cost savings. Older adults with mental health conditions have poorer health outcomes, higher hospitalization rates, and emergency room visits.[372] While there is an increasing need for mental health services, one barrier to effective treatment is access to mental health services.[373] Ensuring access to mental health care in rural communities is challenging as there are fewer mental health providers per capita in nonmetropolitan counties.[374] This coincides with HRSA's second quarter of the fiscal year 2023 designated health professional shortage area (HPSA) quarterly summary, which breaks down the number of HPSAs by primary medical care, dental, and mental health HPSAs based on four categories (rural, non-rural, partial rural, and unknown); and as population HPSAs, geographic HPSAs, or Facility HPSAs. The report does not provide accumulative HPSAs by the four categories.[375] Approximately 65 percent of federally designated health professional shortage areas are located in rural areas, and about 30 percent are located in non-rural areas.[376] The shortage of professionals in rural areas is severe, and the shortage of qualified professionals in combination with geographic limitations only exacerbates the mental health crisis in older adults.[377] While there are disparities in the availability of the behavioral workforce between rural and nonrural areas, counselors are integral to providing care in rural areas.[378]

7. Clinical Laboratory Fee Schedule

In section III.D of this proposed rule, we discuss statutory revisions to the data reporting period and phase-in of payment reductions under the CLFS. In accordance with section 4114 of the CAA, 2023, we are proposing certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for CDLTs that are not ADLTs, we are proposing to update certain definitions and revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2024. The CAA, 2023 delays the next data reporting period under the CLFS for CDLTs that are not ADLTs by 1 year, that is, it requires the next data reporting period for these tests to take place during the period of January 1, 2024 through March 31, 2024. Subsequently, the next private payor rate-based CLFS update for these tests will be effective January 1, 2025, instead of January 1, 2024. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the CAA, 2023 amendments. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2023, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2022, and for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017 through March 31, 2017). In addition, as discussed in section III.D. of this proposed rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the CAA, 2023 amendments to the data reporting period will delay using updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, it is uncertain whether the delay in data reporting will result in a measurable budgetary impact. In other words, to assess the impact of delayed reporting and subsequent implementation of updated CLFS rates, we will need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories, and calculating the updated CLFS rates.

Regarding the conforming changes to our requirements for the phase-in of payment reductions that we are proposing in this rule, we note that for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. Based on data reported in the 2017 data collection period, we estimate 14.8 percent (191) of tests on the CLFS may be subject to the full 15 percent phase-in reduction in CY 2024.

8. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising Practitioners

As discussed in section III.E. of this proposed rule, we are proposing revisions to §§ 410.47 (PR) and 410.49 (CR/ICR) to codify the statutory changes made in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BBA of 2018) which permit other specific types of practitioners to supervise these services effective January 1, 2024. The amendments add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS). Accordingly, we are proposing additions and revisions to the PR and CR/ICR regulations to reflect these statutory amendments.

To assess the potential impact from expanding the types of practitioners that may supervise PR/CR/ICR we searched the literature for articles that evaluated the utilization rates of PR, CR and ICR to determine the historical utilization trends of these services as well as known barriers to utilization. Based on historical utilization trends as well as barriers to utilization discussed in the literature, we do not expect the proposed changes to make a significant impact on the Medicare program.

Nishi et al. (2016) investigated the number of Medicare beneficiaries with COPD who received PR from January 1, 2003, to December 31, 2012. Their results included both individuals who had experienced hospitalizations for COPD and those who were outpatients

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[371] *https://onlinelibrary.wiley.com/doi/full/10.1002/jcad.12409?casa_token=z412GCn3OuYAAAA%3AHO3p-cHeiVrLww0dZjTkIcuCbwMxvYtRUo4aj8AwB-tq2w_ZJV11gGpWW-oxilDK3awU0xIc2XKMnKhtAQ#jcad12409-bib-0003.*

[372] *https://onlinelibrary.wiley.com/doi/full/10.1002/jcad.12409?casa_token=z412GCn3OuYAAAA%3AHO3p-cHeiVrLww0dZjTkIcuCbwMxvYtRUo4aj8AwB-tq2w_ZJV11gGpWW-oxilDK3awU0xIc2XKMnKhtAQ#jcad12409-bib-0005.*

[373] *https://psycnet.apa.org/fulltext/2020-75725-002.html.*

[374] *https://psycnet.apa.org/record/2018-25164-007.*

[375] *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[376] *https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport.*

[377] *https://psycnet.apa.org/fulltext/2020-75725-002.html.*

[378] *chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2016/09/RHRC_DB160_Larson.pdf.*

only. The number of unique patients with COPD who initially participated in PR during the study period was 2.6 percent in 2003 (before conditions of coverage at § 410.47 were established) and 2.88 percent in 2012 (after conditions of coverage at § 410.47 were established).[379] In 2019, *Spitzer, et al.* published an article based on Medicare claims data from 2012, finding that 2.7 percent of eligible Medicare beneficiaries received PR within 12 months of hospitalization with COPD.[380] Using claims data from fee-for-service Medicare beneficiaries hospitalized for COPD in 2014, *Lindenauer et al.* (2020) reported that only 3 percent initiated PR within 1 year of their hospital discharge.[381] Taken together, this data informs us that utilization of PR in the Medicare population is very low.

Million Hearts® 2027, a national initiative co-led by the Centers for Disease Control and Prevention (CDC) and CMS to prevent 1 million preventable cardiovascular disease (CVD) events in the next 5 years,[382] includes a goal of increasing use of CR and states that CR participation rates remain low, ranging from 19 percent to 34 percent.[383] Fleg and colleagues (2020) report that less than 25 percent ''of eligible patients participate in CR'' with a smaller proportion completing 36 sessions as recommended.[384] In their 2022 article, Varghese and colleagues state that less than 30 percent of eligible patients participate in CR in the United States.[385] *Husaini and colleagues* (2022) analyzed a sample of Medicare fee-for-service claims between 2012 and 2016 and reported that within 1 year of a qualifying event, 16 percent of patients completed one or more CR session and 0.1 percent of patients completed one or more ICR sessions. They observed an increase of combined CR and ICR utilization from 14 percent (patients with qualifying events in 2012) to 18 percent (patients with qualifying events in 2015).[386] Taken together, this data informs us that utilization of CR and ICR is low, although not as low as PR.

Underutilization of PR, CR and ICR has been attributed to numerous factors as described by *Fleg et al.* ''including a lack of referral or strong recommendation from a physician and inadequate follow-up or facilitation of enrollment after referral. Financial issues such as limited or absent health insurance coverage and the inability to afford copayments, even when insured, also limit CR/PR participation as do conflicting work and home responsibilities and distance and transportation difficulties. Social and cultural factors, including the lack of gender and racial diversity among CR/PR staff, language and cultural barriers, and lack of program availability and access are additional challenges . . . Many eligible patients are also commonly perceived as too frail . . .'' [387] *Husaini et al.* (2022) reinforce the impact of similar factors in CR underuse. They cite ''lower reimbursements relative to cost and variability in access'', physician ''skepticism over benefit and a primary emphasis on cardiac medications and procedures'', and patient ''reluctance or inability to commit 3–6 hr/wk for 8–12 wk to CR, logistical (transportation, work, etc) or financial impediments, a preference for exercise/rehabilitation at home, fear of failure, and physical limitations.'' [388]

While the expansion of supervision requirements to include nonphysician practitioners could offer greater flexibility for PR and CR programs to operate, the barriers to utilization as described by *Fleg and colleagues* (2020) and *Husiani and colleagues* (2022) are widespread and complex and low participation in PR, CR and ICR has remained steady for many years. We do not believe the expansion of supervising practitioners is likely to address these barriers. Therefore, we do not anticipate any significant increase in utilization of PR, CR and ICR services and subsequent impact to the Medicare program or interested parties.

9. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.F. of this proposed rule, we are proposing allowing periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary through the end of CY 2024, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met.

We believe the Part B cost impact of this flexibility for the use of telecommunications will be minimal because we do not expect that these flexibilities will increase the frequency with which medically necessary assessments are furnished.

10. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2023, 10.9 million Medicare beneficiaries receive care from a health care provider in one of the 456 ACOs participating in the Shared Savings Program, the largest value-based care program in the country. The Shared Savings Program proposed policies advance Medicare's overall value-based care strategy of growth, alignment, and equity, with many proposals overlapping these categories. The proposed policies in this proposed rule are incremental refinements to the broader changes finalized in the CY 2023 PFS final rule (87 FR 69777 through 69968). Those changes were designed to reverse recent trends where

[379] Nishi SP, Zhang W, Kuo YF, Sharma G. Pulmonary Rehabilitation Utilization in Older Adults With Chronic Obstructive Pulmonary Disease, 2003 to 2012. J Cardiopulm Rehabil Prev. 2016;36(5):375–382. doi: 10.1097/HCR.0000000000000194.

[380] Spitzer KA, Stefan MS, Priya A, et al. Participation in pulmonary rehabilitation after hospitalization for chronic obstructive pulmonary disease among Medicare beneficiaries. *Ann Am Thorac Soc.* 2019;16:99–106. DOI: 10.1513/AnnalsATS.201805–332OC. PMID: 30417670; PMCID: PMC6344454.

[381] Lindenauer PK, Stefan MS, Pekow PS, et al. Association Between Initiation of Pulmonary Rehabilitation After Hospitalization for COPD and 1-Year Survival Among Medicare Beneficiaries. *JAMA.* 2020;323(18):1813–1823. doi:10.1001/jama.2020.4437.

[382] *https://millionhearts.hhs.gov/about-million-hearts/index.html.*

[383] *https://millionhearts.hhs.gov/about-million-hearts/optimizing-care/cardiac-rehabilitation.html.*

[384] Fleg JL, Keteyian SJ, Peterson PN, Benzo R, Finkelstein J, Forman DE, Gaalema DE, Cooper LS, Punturieri A, Joseph L, Shero S, Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil. Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[385] Varghese MS, Beatty AL, Song Y, et al., Cardiac Rehabilitation and the COVID–19 Pandemic: Persistent. Declines in Cardiac Rehabilitation Participation and Access Among US Medicare Beneficiaries. Circ Cardiovasc Qual Outcomes. 2022;15:e009618. DOI: 10.1161/CIRCOUTCOMES.122.009618.

[386] Husaini M, Deych E, Racette SB, et al. Intensive Cardiac Rehabilitation Is Markedly Underutilized by Medicare Beneficiaries: RESULTS FROM A 2012–2016 NATIONAL SAMPLE. J Cardiopulm Rehabil Prev. 2022 May 1;42(3):156–162. doi: 10.1097/HCR.0000000000000632. Epub 2021 Sep 9. PMID: 34508035.

[387] Fleg JL, Keteyian SJ, Peterson PN, Benzo R, Finkelstein J, Forman DE, Gaalema DE, Cooper LS, Punturieri A, Joseph L, Shero S, Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil. Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[388] Husaini M, Deych E, Racette SB, et al. Intensive Cardiac Rehabilitation Is Markedly Underutilized by Medicare Beneficiaries: RESULTS FROM A 2012–2016 NATIONAL SAMPLE. J Cardiopulm Rehabil Prev. 2022 May 1;42(3):156–162. doi: 10.1097/HCR.0000000000000632. Epub 2021 Sep 9. PMID: 34508035.

program participation had plateaued, higher spending populations were increasingly underrepresented in the program since the change to regionally-adjusted benchmarks, and access to ACOs appeared inequitable as evidenced by data indicating underserved populations are less likely to be assigned to a Shared Savings Program ACO, and to encourage growth of ACOs in underserved communities.

The changes to the Shared Savings Program regulations finalized with the CY 2023 PFS final rule were designed to increase program participation for new ACOs through the AIP option intended to promote health equity, and provide ACOs greater choice in the pace of progression to performance-based risk; sustain program participation by reducing the effect of ACO performance on benchmark updates and benchmark rebasing; mitigate the bias in regional expenditure calculations that benefits ACOs electing prospective assignment; strengthen incentives for ACOs serving high risk and high dual populations; improve the risk adjustment methodology to better account for medically complex, high cost beneficiaries while continuing to guard against coding initiatives; increase opportunities for low revenue ACOs in the BASIC track to share in savings by allowing ACOs that do not meet the minimum savings rate (MSR) requirement to share in savings at a lower rate; encourage ACOs to transition more quickly to all-payer quality measure reporting; update the ACO beneficiary assignment methodology; and reduce administrative burden on ACOs. The proposed changes to Shared Savings Program policies in this proposed rule include modifications designed to further these goals in concert with implementation of certain changes finalized in the CY 2023 PFS final rule, which are applicable for agreement periods beginning on January 1, 2024, and in subsequent years.

On average, updated benchmarks would marginally increase as a result of the proposal to modify the calculation of the regional component of the blended update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year (PY) by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth (section III.G.4.b of this proposed rule). This change is expected to increase the regional update factor amount in certain cases where an ACO may operate in a regional service area with rapid change in the average prospective HCC risk score for the FFS assignable beneficiary population. The current methodology for calculating the regional update factor risk adjusts county-level FFS expenditures in an ACO's regional service area by Medicare enrollment type by dividing average county-level FFS expenditures for assignable beneficiaries in the county by the average prospective HCC risk score for both the performance year and BY3. The expenditure growth between BY3 and the performance year calculated using risk-adjusted regional expenditures could therefore be reduced by large increases in average prospective HCC risk scores in the ACO's regional service area that would only be partly offset by the increase in prospective HCC risk score growth for the ACO's assigned beneficiary population due to the cap on ACO assigned beneficiary prospective HCC risk score growth when updating the benchmark between BY3 and the performance year. The proposed adjustment, applicable for agreement periods beginning on January 1, 2024, and in subsequent years, would effectively strengthen the regional portion of the three-way blended update factor and help to limit losses ACOs may face when operating in regional service areas with high risk score growth and a beneficiary population that becomes more medically complex between BY3 and the performance year, increasing incentives for ACOs to form or continue participation in such areas. By utilizing a market share adjusted cap to account for ACO market share in the ACO's regional service area, the proposed adjustment would still retain a disincentive against coding intensity for ACOs that may have a high market share in their region and consequently have greater influence on regional service area risk score changes. For example, this feature of the proposal would help dissuade such ACOs from attempting to artificially increase their benchmark by selectively serving lower risk beneficiaries and increasing the intensity of diagnoses submitted for those beneficiaries.

Analyses described in the section III.G.4.b.(2) of this proposed rule, surrounding tables 33 and 34, provide the basis for estimating the impact for the proposal to cap regional service area risk score growth. Analysis of average prospective HCC risk score changes at the Hospital Referral Region (HRR) level over an extended 2007 to 2021 historical period consistently indicated that risk score changes would be highly unlikely to exceed the proposed cap in the first two years of an ACO's agreement period but would increase somewhat as the 5-year agreement period progresses. The analysis also notably showed that average prospective HCC risk score variation increased markedly in 2020 and 2021 with the COVID–19 PHE.[389] The 11 percent of ACOs simulated to be impacted by the proposed adjustment in PY 2021 (a mix of ACOs with 2-year and 3-year gaps between their respective BY3 and the simulated PY 2021) is therefore anticipated to overstate variation expected in agreement periods that start on January 1, 2024 or later.

Based on the simulation in the context of the longer-run HRR data, we project that starting in 2024 the proposed adjustment would impact less than 1 percent of ACOs in PY1 of an agreement period, between 5 to 7 percent of ACOs by PY3, and up to 10 to 15 percent of ACOs by PY5. The adjustment for ACOs that are simulated to be impacted is relatively small, increasing updated benchmarks by about 0.2 percent up to 0.4 percent on average by PY5, but with the potential for up to a net adjustment of about 1.5 percent in extreme scenarios. The estimated cost from additional shared savings payments resulting from these adjustments totals $370 million over 10 years as shown in Table 109.

[389] Public use data on Medicare Geographic Variation—by Hospital Referral Region, used for this analysis, is available at *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-geographic-comparisons/medicare-geographic-variation-by-hospital-referral-region*.

TABLE 109: Projected Impact of Proposed Adjustment Factor to Apply Risk Score Cap to Regional Portion of Blended Update Factor Calculation ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	10	10	20	40	70	50	20	40	40	70	**370**
Estimate Range:											
Low Estimate	0	0	10	20	40	40	20	20	30	40	**220**
High Estimate	10	20	30	60	90	80	40	50	60	100	**540**

A material, albeit uncertain impact, is also estimated for the proposals to (a) use a rolling 3-year historical period instead of contemporary performance to calculate the 40th percentile of the MIPS Quality performance category scores starting in PY 2024 and (b) the proposal to use the higher of the ACO's health equity adjusted quality performance score or the 40th percentile MIPS Quality performance category score across all MIPS Quality performance scores if measure suppression is required. It is likely that MIPS Quality performance will improve at least marginally over time and therefore the historical performance could produce a target that effectively is lower than the contemporary 40th percentile stipulated at baseline. The effective reduction in the threshold when using the historical MIPS scores, combined with the 'higher of' proposal when suppression is necessary, are assumed to effectively reduce the quality target by 0 to 5 percentage points (mode 1.5 percentage points), which would produce an estimated $110 million in additional shared savings payments over 10 years, as shown in the Table 110.

TABLE 110: Projected Combined Impact of Quality Proposals to (a) Use Rolling 3-Year Historical Period to Calculate the 40th Percentile of the MIPS Quality Performance Category Scores and (b) Use the 'Higher Of Value' When Measures are Suppressed ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	0	10	10	10	10	10	10	10	20	20	**110**
Estimate Range:											
Low Estimate	0	0	0	0	0	0	0	0	0	0	**0**
High Estimate	0	30	30	30	40	40	30	40	40	40	**320**

The impact is also estimated to be material for the proposal to mitigate the impact of the negative regional adjustment on the benchmark. In the CY 2023 PFS final rule, CMS finalized changes applicable for agreement periods beginning on January 1, 2024, and in subsequent years, that would reduce the cap on negative regional adjustments from 5 percent to 1.5 percent and provide an offset factor to gradually decrease the negative regional adjustment amount as an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective HCC risk score increases, or both. Removing the regional adjustment entirely, when the ACO's regional adjustment amount (expressed as a single per capita value) is negative, would incrementally increase benchmarks for higher spending ACOs (increasing shared savings payments) but would also improve the incentive for higher spending ACOs to join the Shared Savings Program and drive down unnecessary spending. For a high cost estimate we conservatively assume no new participation is generated in response to this change and estimate the higher benchmarks would generate about $1.8 billion in additional shared savings payments partly offset by about $1.6 billion in reduced spending in response to improved incentives. For a mean estimate we additionally assume 10 percent growth in participation from new high spending ACOs leading to about $490 million net savings over 10 years.[390] For a low cost estimate we instead assume 20 percent growth in participation from high spending ACOs leading to about $1.2 billion in net savings over 10 years. Table 111 shows these estimates over the 2024–2033 window.

[390] Elimination of overall negative regional adjustments, under the proposed approach, would likely generate participation growth from ACOs that will face significant negative adjustments despite the changes from the CY 2023 PFS final rule to reduce the impact of the negative regional adjustment, but also from other prospective high spending ACOs that may have difficulty estimating the relief they will ultimately receive from the offsets applicable to agreement periods beginning on January 1, 2024, and in subsequent years. Eliminating overall negative regional adjustment entirely would materially improve the business case for participation from ACOs in the former category and may at least optically improve the business case for ACOs in the latter category without actually incurring cost to the program by increasing their benchmarks.

TABLE 111: Projected Impact of Proposal to Mitigate the Impact of Negative Regional Adjustment on Benchmarks ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	0	30	10	-20	-70	-110	-100	-70	-90	-70	**-490**
Estimate Range:											
Low Estimate	-10	-10	-40	-80	-130	-200	-200	-180	-200	-170	**-1,220**
High Estimate	10	60	50	30	0	-20	0	30	20	30	**210**

The proposal to specify the use of the CMS–HCC risk adjustment model(s) applicable to the calendar year corresponding to the performance year to calculate a Medicare FFS beneficiary's prospective HCC risk score for the performance year, and for each benchmark year of the ACO's agreement period for agreement periods beginning January 1, 2024, and in subsequent years, is anticipated to remove a potential bias that may otherwise reduce benchmarks particularly for ACOs with beneficiaries exhibiting higher average renormalized risk scores at baseline. An increase in average shared savings payments to ACOs that would have participated regardless of this proposed modification is expected to ultimately be more than offset by additional savings from increased participation from ACOs serving high risk beneficiaries that would have otherwise dropped out or avoided entering the Shared Savings Program under the current approach to calculating prospective HCC risk scores. Net savings are expected to be greater at the end of the 10 year scoring window because residual savings from added participation would grow, whereas benchmarks would not be as impacted in the later part of the scoring window because there is lower likelihood that later agreement periods would have been impacted by changes in the CMS HCC risk adjustment methodology. Table 112 shows these estimates over the 2024–2033 window.

TABLE 112: Projected Impact of Proposal to Use Uniform Approach to Calculate Risk Scores in the Shared Savings Program Benchmark Calculations ($ Millions)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact Estimate	10	20	60	100	140	-70	-130	-180	-160	-110	**-320**
Estimate Range:											
Low Estimate	10	-10	10	30	50	-120	-200	-270	-280	-260	**-1,040**
High Estimate	20	80	130	190	240	70	10	-50	-40	-20	**630**

An overall net impact is difficult to quantify for the proposed changes in section III.G.3.a of this proposed rule, to incorporate use of a new third step in the step-wise beneficiary assignment methodology and the proposed changes to identification of the assignable beneficiary population. These proposed changes are not currently estimated to have a net impact on program spending in either direction. Impacts on benchmark calculations for individual ACOs would likely be mixed and of relatively limited magnitude. The proposed changes could allow some ACOs to increase efficiency by utilizing more non-physician clinicians in delivering primary care without jeopardizing assignment. On the other hand, they could marginally increase shared savings payments for efficiencies that currently would accrue entirely to the program as spillover effects on beneficiaries unable to be assigned. The overall impact is currently anticipated to be roughly neutral. We will continue to analyze data on the potential impact of these proposed changes on existing ACOs, and will monitor effects if the proposals are finalized and implemented in future agreement periods.

The remaining proposed changes to the Shared Savings Program regulations are not estimated to have an impact on program spending at the aggregate level. These proposed changes include modifying the definition of primary care services for purposes of determining beneficiary assignment, recalculating the prior savings adjustment for changes in the amount of savings earned by an ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or changes in the amount of savings or losses for a benchmark year as a result of the issuance of a revised initial determination of financial performance, expanding quality reporting options to include Medicare CQMs, requiring reporting of MIPS PI performance category for all eligible clinicians participating in ACOs, and using beneficiary counts instead of person years in health equity adjustment calculations, as well as proposals to further refine AIP policies, revise program eligibility requirements, and make technical changes.

b. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory

payment model. The following proposals require the use of our authority under section 1899(i) of the Act: the proposed modifications to the calculation of regional component of the three-way blended update factor to cap regional service area risk score growth for symmetry with the ACO risk score growth cap, as described in section III.G.4.b of this proposed rule and the refinements to AIP policies as described in section III.G.5. of this proposed rule. Further, certain existing policies adopted under the authority of section 1899(i)(3) of the Act that depend on use of the assigned population and assignable beneficiary populations, would be affected by the proposed addition of a new third step of the beneficiary assignment methodology and the proposed revisions to the definition of assignable beneficiary, described in section III.G.3. of this proposed rule, including the following: the amount of advance investment payments; factors used in determining shared losses for ACOs under two-sided models (including calculation of the variable MSR/MLR based on the ACO's number of assigned beneficiaries, and the applicability of the extreme and uncontrollable circumstances policy for mitigating shared losses for two-sided model ACOs); and calculation of the ACPT, regional and national components of the three-way blended benchmark update factor. When considered together these changes to the Shared Savings Program's payment methodology are expected to improve the quality and efficiency of items and services furnished under the Medicare program by improving the ability for ACOs to sustain effective participation in regions with changing populations and increasing the overall proportion of Medicare beneficiaries assigned to ACOs, and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule we estimated that the projected impact of the payment methodology that incorporates all finalized changes from that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies that require section 1899(i)(3) of the Act authority (see 87 FR 70195 and 70196). The marginal impact of the proposed changes discussed in this proposed rule is estimated to be $330 million lower net spending over the ten year window for all new proposals combined, including the proposal to cap an ACO's regional service area risk score growth and the proposals to add a new third step to the beneficiary assignment methodology and to revise the approach to identify the assignable beneficiary population. Therefore, we believe the requirements of section 1899(i)(3)(B) of the Act would not be violated by these relatively minor changes to program spending.

We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

11. Medicare Part B Payment for At-Home Preventive Vaccine Administration Services

In section III.H.3.c of this proposed rule, we propose to maintain the additional payment when a COVID–19 vaccine is administered in a beneficiary's home under certain circumstances, and to extend this payment to the administration of a pneumococcal, hepatitis B or influenza vaccines.

We estimated the impact of the proposal to maintain the additional payment for in-home COVID–19 vaccine administrations and to expand the policy to the administration of all Part B preventive vaccines. For this estimate, we analyzed CY 2021–2022 utilization of HCPCS code M0201 for the providers and suppliers that billed it, along with their utilization of the relevant preventive vaccine administration codes. During this period, the in-home additional payment was billed about 200,000 times by roughly 1,500 different providers and suppliers. For those providers or suppliers who administered COVID–19 vaccine in the home in 2021–2022, HCPCS code M0201 was billed about 2 percent of the time they administered any COVID–19 vaccination. Total Medicare payments for this service in 2021 and 2022 were $4 million and $3 million, respectively.

While we expect that in-home administrations of COVID vaccines will continue into CY 2024, we note that the overall utilization of the COVID–19 vaccine was significantly lower in 2022 than in 2021, and future utilization is unknown. Further, if we apply the prevalence of the utilization of HCPCS code M0201 for in-home administration of the COVID–19 vaccine to the utilization of the other three Part B preventive vaccinations, it would result in higher spending of roughly $1–2 million. Therefore, the overall estimated impact of this proposal is increased spending of less than $5 million in 2024. We note that our analysis assumed that there would be no additional providers or suppliers who would decide to begin providing these vaccines at home for CY2024, given that COVID–19 PHE ended on May 11, 2023

12. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

a. Effects on Beneficiaries

We propose to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) Extend the flexibilities allowed during the PHE for the COVID–191135 waiver event by 4 years (or until December 31, 2027), (2) update the MDPP payment structure to pay for beneficiary attendance on a fee-for-service basis while retaining the diabetes risk reduction performance payments, (3) remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition, and (4) remove most references to, and requirements of, the Ongoing Maintenance Sessions given that eligibility for these services will end on December 31, 2023. We anticipate that these proposed changes will have a positive impact on beneficiaries' access to MDPP services by increasing the number of MDPP eligible organizations that enroll in Medicare as MDPP suppliers and, more importantly, increasing beneficiary access to the Set of MDPP services by allowing them continued access to MDPP through a live in-person or virtual classroom (or a combination of both modalities). The proposed changes would also remove barriers specific to attending these classes solely in-person, which may include a lack of MDPP suppliers in certain communities and challenges related to beneficiary logistics concerning course attendance.

These proposed modifications address MDPP supplier and beneficiary needs based upon available monitoring and evaluation data received to date,

feedback from Medicare Advantage plans and existing MDPP suppliers, and feedback from beneficiary focus groups. The proposed changes are also in response to comments from interested parties made through public comments in response to prior rulemaking.

During the initial rulemaking for the MDPP expanded model, we sought to ensure that MDPP would be delivered in-person, in a classroom-based setting, and within an established period of service to maintain consistency with the original DPP model test. At the time, priority was placed on establishing a structured expanded model that, when delivered within the confines of the rule, would create the least risk of fraud, waste, and abuse, increase the likelihood of success, and maintain the integrity of the data collected for evaluation purposes.

However, circumstances such as the PHE for COVID–19 led us to make changes to the MDPP expanded model through implementation of an Emergency Policy for MDPP that allows for temporary flexibilities while prioritizing availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by such section 1135 waiver events. For example, in the CY 2021 PFS, we finalized the regulations in the March 31st COVID–19 IFC to amend the MDPP expanded model to revise certain MDPP policies during the COVID–19 PHE as well as any future 1135 waiver events where such 1135 waiver event may cause a disruption to in-person MDPP service delivery. These flexibilities allowed beneficiaries to either continue to have access to MDPP through participation in virtual sessions, pause an in-person MDPP class and resume with the most recent attendance session of record, or restart MDPP from the beginning in accordance with the March 31st COVID–19 IFC (85 FR 19230).

When establishing these flexibilities, we could not predict that the COVID–19 PHE would continue for over 3 years. Although beneficiary participation decreased significantly during the initial year of the COVID–19 PHE, MDPP participation has slowly increased since 2021. As this additional modality of delivery has helped improve supplier access to beneficiaries, removing the PHE flexibilities and suppliers' ability to deliver MDPP virtually after 3 years would not only be disruptive to suppliers, it may in-fact be detrimental to the operations of the MDPP expanded model.

During the COVID–19 PHE, we permitted virtual delivery of the Set of MDPP services by MDPP suppliers who were recognized by the CDC with Diabetes Prevention Recognition Program (DPRP) in-person delivery mode, but did not permit suppliers who were only recognized by the CDC with either online or distance learning delivery modes. Although we finalized in the CY 2021 PFS that suppliers had to be prepared to return to in-person delivery when the PHE ended, the PHE lasted for over 39 months. Therefore, returning to a solely in-person, pre-PHE delivery model may not be as simple for some suppliers.

Post-PHE, many beneficiaries and suppliers have reported the desire to continue utilizing virtual delivery of MDPP for a wide range of reasons. Maintaining suppliers' ability to offer both synchronous virtual (distance learning) and in-person MDPP may increase beneficiary uptake of these services. It is important to note that permitting virtual delivery of MDPP throughout the PHE has not resulted in a spike in MDPP utilization. A reason for a lack of beneficiary participation may be tied to the fact that suppliers still had to maintain the ability to deliver in-person services (rent or own physical space), while some suppliers were unfortunately unable to pivot to virtual delivery during the COVID–19 PHE for a variety of reasons.

Current data depict that the most impactful MDPP results correspond to attending MDPP sessions virtually or through utilizing a hybrid approach (attending classes both virtually and in-person). Interim MDPP evaluation data illustrated that average participant weight loss is 5.1 percent since the expanded model launched on April 1, 2018, surpassing the expanded model's weight loss goal of 5 percent. In addition, the interim evaluation data show that, 53 percent of MDPP participants attained the 5 percent weight-loss goal, and 24.6 percent attained the 9 percent weight-loss goal.[391] Aligning with the Diabetes Prevention Program (DPP) model test [392] and studies on the National DPP,[393] [394] MDPP participants who attended more sessions lost more weight. For example, among beneficiaries who attended at least 9 sessions, 64 percent met the 5 percent weight loss goal and 30 percent met the 9 percent weight loss goal. For MDPP participants impacted by the COVID–19 PHE, evaluation data confirm significantly increased weight loss accompanied with a higher number of sessions attended by participants completing the expanded model in 2021, with these participants attending primarily virtual sessions or a mixture of virtual and in-person sessions.

To date, there have been no preliminary indications that the synchronous virtual delivery of MDPP has limited supplier instruction or beneficiary success, as defined by achievement of the 5 percent weight loss goal. However, it is too early to determine the impact of synchronous virtual delivery of MDPP on other outcomes such as cost-savings or incidence of diabetes. MDPP has been fundamentally limited by low beneficiary participation and corresponding small sample sizes. We believe that an increase in supplier uptake, which may be accomplished through our proposal to maintain more options of MDPP delivery modalities, will result in an increase in beneficiary enrollment. This will be critical to conducting robust programmatic evaluations, including a potential future certification of the synchronous virtual delivery of MDPP.

To assist with our ability to improve monitoring and evaluation of the synchronous virtual delivery of MDPP, we have proposed a new HCPCS G-code specific to distance learning. Additionally, extending the flexibilities allowed during the PHE for COVID–19 by 4 years would improve MDPP eligible organizations' MDPP service delivery opportunities due to the use of multiple modalities.

b. Effects on the Market

While we acknowledge that additional changes will likely be necessary to improve beneficiary access to MDPP, we anticipate that the enhancements proposed in this rule are likely to result in an increase of MDPP suppliers and increased beneficiary access to the Set of MDPP services. We anticipate that this will assist in contributing to a reduction of the incidence of diabetes among eligible Medicare beneficiaries, and in particular, those residing in underserved communities. Currently, there are approximately 786 in-person organizations nationally that are eligible to become MDPP suppliers based on

[391] MDPP 2nd Annual Evaluation Report.

[392] RTI International. *Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring: THIRD ANNUAL REPORT.* March 2017. *https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf.*

[393] Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346(6):393–403. doi:10.1056/NEJMoa012512.

[394] Diabetes Prevention Program Research Group. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program Outcomes Study. *Lancet Diabetes Endocrinol.* 2015;3(11):866–875. doi:10.1016/S2213-8587(15)00291-0.

their preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) status. However, only 25 percent of eligible in-person organizations are participating in MDPP, and only one-third of MDPP suppliers have submitted MDPP-related claims. Through updating the payment structure to one that is similar to those of existing CMS Medicare Preventive Services such as the Intensive Behavioral Counseling for Obesity, the MDPP claims submission process may be more intuitive for existing Medicare suppliers. In addition, we anticipate that simplifying the MDPP payment structure will address some of the complexities related to the process for submitting claims, while encouraging more suppliers to submit claims for MDPP due to a reduced set of codes.

Since MDPP was established through the CY 2017 PFS, we have consistently heard from interested parties that we should include virtual delivery of MDPP as part of the expanded model test, which would increase beneficiary access to the Set of MDPP services while providing flexibility of where both a beneficiary may take the course and from where a supplier may deliver the course. Although we did not allow for a fully virtual delivery of MDPP until the COVID–19 PHE, we did allow a limited number of virtual make-up sessions, which could be delivered either synchronously or asynchronously. The rationale for allowing a limited number of virtual make-up sessions was due to the fact that the data used to certify MDPP were based upon in-person delivery, thereby fully virtual delivery was arguably outside the scope of certification.

The COVID–19 PHE led CMS to establish MDPP flexibilities that allowed fully virtual delivery of the Set of MDPP services by suppliers. We established several emergency flexibilities within the IFC–1 that removed the limit on the number of virtual makeup sessions, and in the CY 2021 PFS, we finalized the MDPP flexibilities from the IFC–1 while establishing the MDPP Emergency Policy that allowed for virtual delivery of MDPP, including virtual weight collection. However, the CY 2021 PFS stated that MDPP suppliers must retain the capacity to deliver the Set of MDPP services in-person, precluding organizations with CDC DPRP recognition solely in the distance learning or online modalities from participating in MDPP during the COVID–19 PHE. Interested parties commented that some beneficiaries may have limited access or ability to use the technology required for participation in virtual MDPP sessions.

In the CY 2022 PFS, although outside the scope of rule, interested parties recommended that we continue the virtual option following the end of the COVID–19 PHE to assist in increasing access to MDPP, especially for those with transportation needs as well as for beneficiaries in rural and low-income communities, who may suffer from a lack of in-person suppliers. As a result of these recommendations, in this rule, we are proposing to extend the PHE flexibilities, specific to allowing synchronous virtual delivery of MDPP, also known as distance learning.

Currently, there are numerous large geographic gaps of MDPP supplier locations, and synchronous virtual delivery may be part of the solution to increasing the accessibility of MDPP to more beneficiaries. It is unclear how the market will respond to the proposed extension of the PHE flexibilities allowed during the COVID–19 PHE, especially since we are still requiring suppliers to have and maintain an in-person DPRP recognition, but we believe organizations will be ready to engage in the delivery of the Set of MDPP services either in-person, through distance learning, or through a combination of in-person and distance learning. We also believe that having more flexibility in how the Set of MDPP services are delivered will make MDPP more accessible to beneficiaries, particularly those who live in rural areas or in communities with gaps in MDPP supplier locations.

c. Payment for MDPP Services

Regulations at § 414.84 specify MDPP suppliers may be eligible to receive payments for furnishing MDPP services and meeting performance targets related to beneficiary weight loss and/or attendance. However, we have consistently heard from suppliers and interested parties that the MDPP performance-based payment structure has been confusing to some suppliers, including those new to Medicare as well as existing suppliers. Approximately 37 percent of MDPP suppliers have submitted FFS claims for MDPP.[395] Confusion with claims submission has been due, in part, to the MDPP payment structure, which pays for performance-based milestones versus paying for traditional fee-for-service. The performance-based payment structure requires 15 HCPCS G-codes if including ongoing maintenance sessions, and 11 G-codes for the 12-month MDPP service period. Therefore, we are proposing to shift this payment structure to pay for attendance on a fee-for-service basis while retaining the diabetes risk reduction performance milestones, for example 5 percent and 9 percent weight loss as well as the maintenance of the 5 percent weight loss in months 7–12. This proposed streamlined payment structure will allow suppliers to receive a more consistent set of payments for their delivery of the Set of MDPP services and reduce the number of G-codes for easier billing.

We anticipate that this updated payment structure will reduce the upfront beneficiary retention costs while motivating eligible suppliers to enroll in Medicare to become MDPP suppliers and provide the Set of MDPP services to eligible Medicare beneficiaries. In the current MDPP payment structure, suppliers submit claims after the 1st, 4th, and 9th sessions attended during the core sessions interval, and following attendance of the two (2) sessions during each of the core maintenance intervals. Although the proposed per session payment of $25 is less than the current per session payment of $38, suppliers will receive up to 22 payments for attendance in the proposed payment structure compared to seven attendance-based payments, for participants who began participation in 2022 or later, or eleven attendance-based payments for participants whose first core session was in 2021 or earlier. The total attendance-based payments will increase by $54 to $550 in the proposed payment structure, compared to $496 in the current one.

This proposed payment schedule would not only eliminate gaps in payment by providing smaller but more frequent per-session payments, it would also reduce or eliminate some of the coding challenges related to the number of existing HCPCS codes. We have proposed to decrease the one-time performance payments for beneficiary achievement of the 5 percent and 9 percent weight loss goals as well as propose a new HCPCS G-code for the maintenance of the 5 percent weight loss during months 7–12. The proposed total maximum payment of $768 consists of the attendance-based payments and the weight loss performance payments. Although the proposed maximum payment of $768 over a one-year service period is the same as the current maximum payment, we believe this simplified payment structure will lead to fewer claims rejections while encouraging more suppliers to submit MDPP claims for the beneficiaries they serve, as well as

[395] Unpublished data from Acumen LLC, Quarter 4 2022 Quarterly Monitoring Report to CMS.

motivate more eligible organizations enroll in Medicare to participate in MDPP.

d. Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

There are two proposed changes to the Medicare Diabetes Prevention Program (MDPP) which are relevant to this impact analysis. Both changes will be implemented in 2024 if finalized: Simplifying the MDPP payment schedule; and allowing specified Public Health Emergency (PHE) flexibilities to continue for 4 years after the PHE ends—namely, allowing for synchronous virtual delivery of the Set of MDPP services.

Table 113 shows the estimated impact (in millions) of these two proposed changes on Medicare spending:

TABLE 113: Estimated Impact (in millions) of the Two Proposed Changes on Medicare Spending

Year	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Impact on Medicare Spending	$0.3	$0.3	$0.1	$0.0	−$0.2	−$0.8	−$0.7	−$0.6	−$0.5	−$0.3	−$2.4

(b) Assumptions/Notes

- Simplifying the payment schedule will lead to fewer claim denials and more participation from MDPP suppliers . For example, only 55–62% of FFS participants listed in the supplier crosswalks have an associated MDPP claim over the past 2 years, meaning that organizations have submitted data to the CDC as part of their Diabetes Prevention Recognition Program (DPRP) requirements, and also have FFS claims submitted for the same participants for the same sessions recorded in the DPRP data. The proposed payment schedule will reduce the number of HCPCS codes to from 15 to 6 and eliminate some of the coding issues. It will also eliminate the gaps in payment by providing smaller but more frequent per-session payments.
- The average payment per MDPP participant will increase by $150. The new payment schedule will likely lead to more successful claim payment submissions and will motivate MDPP providers to retain participating beneficiaries for longer periods of time.
- In 2022, 551 FFS claims were paid for the initial MDPP session, compared with 514 in 2021. According to counts of new FFS participants, there have been about 700 new entrants per year in recent years. With the implementation of a simpler payment schedule and the extension of PHE flexibilities, we assume that new participation will be more in line with claim payments for HCPCS code G9873 and will increase to 1,000 in 2024 and 1,250 during the following years until the extended flexibilities end. We estimate that there will be 500 new (in-person only) participants each year starting in 2029.
- Since the start of the PHE, synchronous virtual delivery of MDPP services has been more prevalent than in-person delivery. However, given the coding/reporting issues during the PHE, it is difficult to determine how many beneficiaries are still receiving MDPP services in-person. Without the proposed changes, we assume that new participation will be capped at 400 beneficiaries per year.
- For preventing diabetes progression, synchronous virtual delivery of the Set of MDPP services has the same level of effectiveness as in-person delivery. Following 3 years of delivering MDPP almost solely virtually, suppliers and beneficiaries have become adept at utilizing virtual delivery, as many providers in numerous healthcare settings have shifted to utilizing technology. Furthermore, preliminary MDPP data collected during the PHE indicates that beneficiaries have achieved similar weight loss and attendance goals as participants in both the in-person DPP test and MDPP participants who enrolled in MDPP prior to the pandemic. This assumption is revisited in the Sensitivity Analysis section.

(c) Sensitivity Analysis

On March 14, 2016, the Office of the Actuary (OACT) published a certification memorandum setting out the conditions for expansion of the Medicare Diabetes Prevention Program (MDPP), which can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf*. Assumptions about the 10-year cost impacts of virtual delivery of MDPP services takes into account the assumptions of the original certification, and adjusts for diabetes costs in 2023 dollars, and trends those costs over the next 10 years.

Since both the effectiveness and the future participation level of synchronous virtual delivery of MDPP services are largely unknown, Table 114 shows 10-year cost impacts (in millions) of varying levels of effectiveness of the virtual delivery of the Set of MDPP services relative to the in-person delivery of the Set of MDPP services, paired with varying levels of virtual MDPP participation.

TABLE 114: 10-year Cost Impacts (in millions) of Virtual Delivery of MDPP Services

Virtual Beneficiaries Per Year/Effectiveness	25%	50%	75%
1,000	$0.7	−$0.8	−$2.3
2,000	$1.3	−$1.6	−$4.6
3,000	$2.0	−$2.4	−$6.9

As indicated in Table 114, virtual delivery of MDPP services is estimated to produce savings when it is at least 50 percent as effective as in-person delivery.

13. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 1834(q)(2) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA), directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for applicable imaging services furnished in an applicable setting.

As discussed in detail in section III.J. of this proposed rule, since 2015, we have taken a thoughtful, stepwise approach that maximized engagement and involvement of interested parties to implement the statutory provisions set forth in section 1834(q), as added by section 218(b) of the PAMA, using notice and comment rulemaking. As codified at § 414.94, we established the first two components of the AUC statutory requirements—establishment of AUC and mechanisms for consultation. We began to build the parameters for the fourth component, outlier identification and prior authorization, leading to prior authorization, by establishing the priority clinical areas (PCAs). We began implementing the third component, the AUC consultation and reporting requirement, using the ongoing educational and operations testing period. However, as discussed previously in this proposed rule, at this time, we have exhausted all reasonable options for fully operationalizing the AUC program consistent with the statutory provisions as prescribed in section 1834(q)(B) of the Act directing CMS to require real-time claims-based reporting to collect information on AUC consultation and imaging patterns for advanced diagnostic imaging services to ultimately inform outlier identification and prior authorization. As a result, we have proposed to pause implementation of the AUC program for reevaluation and to rescind the current AUC program regulations at § 414.94.

In the CY 2019 PFS final rule (83 FR 59452), we performed an RIA for this program and updated that RIA in the CY 2022 PFS final rule (86 FR 64996). The estimated impacts in the CY 2022 PFS final rule are as follows:

- Cost to ordering clinicians of required AUC consultation: $51,039,109 annually.
- Cost to Medicare beneficiaries for additional office visit time: $54,789,518 annually.
- Cost to ordering clinicians of transmitting consultation information: $94,495,192 annually.
- Cost to furnishing clinicians to update processes to report AUC information: $1,851,356,888 (one time).
- Potential savings to Medicare program from decrease in imaging utilization: $700,000,000 annually.

Table 115 also includes the AUC program-related activities and their corresponding impact estimates. By pausing efforts to implement the AUC program for reevaluation and rescinding the AUC program regulation at § 414.94, the Medicare program may not realize the estimated savings, and clinicians and beneficiaries will not experience the estimated costs.

TABLE 115: AUC Program Related Activities with Impact Estimates From CY2022 PFS

AUC Program Related Activity	CY 2022 PFS Rule Impact Estimate
Impact of required AUC consultations by ordering professional	$51,039,109
Impact to Medicare beneficiaries	$54,789,518
Impact on transmitting orders for advanced diagnostic imaging services	$94,495,192
AUC automated solution	$1,851,356,888
Medicare program impacts associated with advanced diagnostic imaging services	$700,000,000

14. Medicare and Medicaid Provider and Supplier Enrollment Changes

In this section, we discuss the impact of our proposed Medicare provider enrollment revocation provisions and our Medicaid termination database proposal. For all provider enrollment proposals not referenced in this section, we have determined that they would not have an economic impact.

a. Medicare Revocation Reasons

As discussed in section III.J of this proposed rule, we are proposing several new or expanded revocation reasons in § 424.535(a).

First, we propose to expand § 424.535(a)(1) to include instances where the provider or supplier is non-compliant with the enrollment requirements in Title 42. Paragraph (a)(1) would no longer be restricted to non-compliance with the provisions of 42 CFR part 424, subpart P.

Second, new § 424.535(a)(15) would give CMS the authority to revoke enrollment if the provider or supplier, an owning or managing employee or organization thereof, or an officer or director thereof has had a civil judgment under the False Claims Act (31 U.S.C. 3729–3733) imposed against them within the previous 10 years.

Third, § 424.535(a)(16) would permit CMS to revoke enrollment if a provider or supplier, or any owner, managing employee or organization, officer, or director thereof, has been convicted of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

Fourth, we propose in new § 424.535(a)(243) that CMS may revoke an IDTF's, DMEPOS supplier's, OTP's, or HIT supplier's, or MDPP's enrollment based on a violation of any standard or condition in, respectively, §§ 410.33(g), 424.57(c), 424.67(b) or (e), or 424.68(c) or (e), or 424.205(b) or (d).

Based on CMS statistics concerning the average annual amount of Medicare payments a provider or supplier receives, we project a figure of $50,000. We note that we have recently used this figure when estimating the potential savings associated with several new revocation reasons.[396] For purposes of

[396] For example, see the final rule published in the **Federal Register** on November 18, 2022 (87 FR 69404), titled Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings

consistency and accuracy, we propose to use this $50,000 amount in this proposed rule.

Table 116 outlines the estimated annual number of revocations that would ensue with the four aforementioned revocation proposals:

TABLE 116: Estimated Annual Number of Revocations

Proposed Revocation Reason	Number of Revocations
§ 424.535(a)(1)	5
§ 424.535(a)(15)	5
§ 424.535(a)(16)	5
§ 424.535(a)(23)	5
Total	20

These revocations would represent a savings to the Federal Government because Trust Fund dollars would no longer be paid to the revoked providers and suppliers. Accordingly, we project an annual savings to the Federal Government of $1,000,000 ($50,000 × 20 revocations).

b. Medicaid Termination Database

As discussed in section III.J. of this proposed rule, we are proposing certain provisions in 42 CFR part 455 concerning the length of time a provider remains in the Medicaid termination database and how this interacts with the termination periods that States impose upon terminated providers. We do not believe these proposals involve any additional impact or burden on providers or States. In fact, it could result in a reduction of burden because a provider's potential length of time in the termination database would be capped at 10 years, although we have no data available with which to assist us in calculating the possible burden reduction. As a result, since we are uncertain of how much of the burden will be reduced, we are seeking public comments from the public to aid in understanding how to measure said burden reduction.

15. Expand Diabetes Screening and Diabetes Definitions

As discussed in section III.L. in this proposed rule, we propose to: (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test, (2) expand and simplify the frequency limitations for diabetes screening, and (3) simplify the regulatory definition of ''diabetes'' for diabetes screening, Medical Nutrition Therapy (MNT) and Diabetes Outpatient Self-Management Training Services (DSMT).

We anticipate that expanding coverage of diabetes screening to include the HbA1c test and expanding and simplifying the frequency limitations for diabetes screening to result in some additional service utilization, but we also anticipate the additional utilization may be balanced, in part, by potential long term benefits and savings resulting from increased prevention and early detection (allowing for less invasive and more effective treatment). As described earlier in our proposal, Medicare currently covers the Fasting Plasma Glucose (FPG) test and the Glucose Tolerance Test (GTT) for diabetes screening. The HbA1c test does not require fasting and is more convenient than the currently covered FPG and GTT. We also propose to expand and simplify the frequency limitations for diabetes screening by aligning to the statutory limitation of ''not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.''

We estimate our proposal to expand diabetes screening to result in approximately $68.5 million in additional annual expenditures for the Medicare Program. Our estimate is based on the following assumptions. Based on calendar year 2022 actual experience, approximately 27.3 percent of beneficiaries had a blood panel test that did not include the HbA1c test. Medicare currently pays approximately $9.50 per HbA1c test for diabetes management. The Medicare statutory and regulatory eligibility factors for an individual at risk for diabetes (section 1861(yy)(2) of the Act, 42 CFR 410.18(e)) cover much of the current Medicare beneficiary population. We assume that approximately 7.6 million potential additional HbA1c tests for diabetes screening to be billed under our proposal in calendar year 2024 and that the HbA1c test would be billed with a blood panel 95 percent of the time. Our estimate does not reflect secondary effects of the proposed policies, such as increased utilization of preventive screening services, additional follow-up services, and potential offsetting savings (including prevention and more effective treatment through early detection) that may result from these coverage expansions. Secondary effects are difficult to predict, may materialize many years after the intervention and may, in part, offset one another.

We do not anticipate that our proposal to simplify and expand the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT to result in a significant economic impact on the Medicare program. As described earlier, we propose to remove the regulatorily codified clinical test requirements from the definition of ''diabetes'' for diabetes screening, MNT and DSMT and propose a shortened version of the existing definition that would simply define diabetes as diabetes mellitus, a condition of abnormal glucose metabolism. We believe that our proposal will empower health care professionals to apply clinically accurate and appropriate criteria and that we can ensure certain safeguards through medical coding and claims processing instructions. We do not anticipate our proposal to simplify and expand the regulatory definition of ''diabetes'' for diabetes screening, MNT and DSMT to result in a significant economic impact on the Medicare Program because the regulatory simplification would not otherwise change requirements or conditions of coverage and payment.

Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules''.

16. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Section 2003 of the SUPPORT Act)

In section III.M. of this proposed rule, we are proposing several updates to the CMS EPCS Program. We are proposing to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program and to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5). Under this proposal, prescriptions that are prescribed and dispensed within the same legal entity are included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5). This proposal provides flexibility to prescribers and dispensing pharmacies that are the same entity to choose either of the electronic standards available at § 423.160(a)(3)(iii) to conduct e-prescribing appropriate for their internal systems without us having to exclude these prescriptions completely from the CMS EPCS Program. This proposal would affect prescriptions where the prescriber and the dispensing pharmacy are part of the same legal entity. Due to the limitations in identifying these prescriptions in the Prescription Drug Event (PDE) data, the ability to quantify the impact of this proposal is unknown. Please see section III.M.3.b. of this proposed rule for our discussion.

We are proposing to specify how we count prescriptions for the compliance calculation by proposing to use the unique identifier given to a prescription by the pharmacy in the measurement year and included in the Part D claims data. We will count renewals as an additional prescription in the CMS EPCS Program compliance threshold calculation, and we will not count refills as an additional prescription in the CMS EPCS Program compliance threshold calculation unless the refill is the first occurrence of the unique prescription in the measurement year. If each refill included on the original prescription were counted as a separate prescription, we believe there would be an incremental impact on small prescribers. Preliminary analysis of 2021 Part D data shows that approximately 23,000 prescribers would no longer qualify for the small prescriber exception and that approximately 6,900 additional prescribers would be noncompliant.

We are proposing updates to the CMS EPCS Program recognized emergency exception and waiver exception presently found at § 423.160(a)(5)(iii) and (iv) and proposed to be codified at § 423.160(a)(5)(ii) and § 423.160(a)(5)(iii) respectively. We are proposing to have discretion to determine which emergencies trigger the recognized emergency exception starting in the 2024 measurement year and proposing that prescribers to whom the exception applies would be excepted from the CMS EPCS Program requirements for the entire measurement year. We are proposing to modify how we have previously defined ''extraordinary circumstance'' for purposes of the waiver exception. We propose that an ''extraordinary circumstance'' means a situation outside of the control of a prescriber that prevents the prescriber from electronically prescribing a Schedule II–V controlled substance that is a Part D drug and does not exclude ''cases of an emergency or disaster.'' In cases of extraordinary circumstances, we are proposing the timeframe that would be covered by a waiver authorized under the CMS EPCS Program to be the entire measurement year. We are proposing that a prescriber has a period of 60 days from the date of the notice of non-compliance to request a waiver. Approved waivers would apply to prescriptions written by a prescriber for the entire measurement year, and the waiver would expire on December 31 of the applicable measurement year. Although we are modifying the situations in which a prescriber can apply for an extraordinary circumstances waiver and limiting the recognized emergencies exception that applies to the CMS EPCS Program, we do not anticipate these proposals to affect many clinicians compared to the current policies. First, we believe that the proposal for CMS to identify which emergencies trigger the recognized emergency exception would still capture the vast majority of emergencies or disasters that affect a prescriber's ability to achieve EPCS compliance and would remove any need for additional prescribers to apply for a waiver. Second, some prescribers who experience an emergency may still meet the 70 percent compliance threshold by the end of the emergency period and would not need to apply for a waiver exception. Finally, we are unable to quantify the additional number of potential disasters or emergencies prescribers might experience due to variability in the number of disasters and emergencies in a given measurement year. Therefore, we are not increasing our assumption that 100 waiver requests would be submitted to the CMS EPCS program, as we discussed in the CY 2022 PFS final rule (86 FR 65562).

We are proposing to continue sending non-compliance notices to prescribers identified as non-compliant with the CMS EPCS Program for any individual measurement year, and we do not believe that causes additional costs or will require additional time. Please see section III.M.6. of this proposed rule for our discussion. We do not anticipate the provisions to have any incremental impact on the cost or time associated with prescriber compliance with the electronic prescribing for controlled substances requirement or the cost to interested parties.

17. Proposed Changes to the Regulations Associated With the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS)

As discussed in section III.N.2. of this proposed rule, section 4103 of the CAA amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2024. The ambulance extender provisions are enacted through legislation that is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions legislative provisions. The Congressional Budget Office (CBO)'s estimated cost of these provisions was $55 million in 2023, $91 million in 2024, and $29 million in 2025 (*https://www.cbo.gov/system/files/2023-01/PL117-328_1-12-23.pdf*, p. 17). We are proposing only to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

In addition, as discussed in section III.N.3. of this proposed rule, we are proposing the following changes to the Medicare Ground Ambulance Data Collection Instrument: Adding the ability to address partial year responses from ground ambulance organizations, introducing a minor edit to improve the reporting consistency of hospital-based ambulance organizations, and four technical corrections to typos. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

While we believe that these changes and clarifications will be well received by the ground ambulance interested parties, we do not believe that these changes would have any substantive impact on the cost or time associated

with completing the Medicare Ground Ambulance Data Collection Instrument. We note that the overall length of the Medicare Ground Ambulance Data Collection Instrument will be the same as previously finalized (84 FR 62888) with these changes. Additionally, some of the instructions which we propose to add are intended to improve clarity and may therefore reduce the time the ground ambulance organizations spend addressing the questions.

18. Hospice CoP Changes

a. Permitting MFT and MCH To Serve as Members of the Interdisciplinary Group (IDG)

Under the Medicare Program in accordance with Subtitle C, Section 4121 of the CAA 2023, we are proposing conforming regulations text changes to permit MFT or MHC to serve as members of the IDG. These proposed changes will require hospices to include at least one SW, MFT or MHC to serve as a member of the IDG. Hospices will have the flexibility to determine which discipline(s) are appropriate to serve on the IDG based on the needs of the patients.

b. Modification of the Hospice Personnel Requirements With the Addition of MFT and MHC

Under the Medicare Program in accordance with Subtitle C, Section 4121 of the CAA 2023, we are proposing conforming regulations text changes to permit MFT or MHC to serve as members of the IDG. With the proposed addition of MFT and MHC into the hospice CoPs, it is important to include these new disciplines into the personnel qualifications at § 418.114. However, in section III.C. of this rule, we are proposing to add both MHC and MFT to the provider requirements under 42 CFR subpart B Medical and Other Health Services at §§ 410.53 and 410.54. Therefore, to avoid duplication and confusion between the CoP and the provider requirements under the Medical and Other Health Services provision, we are proposing to add both MHC and MFT to the requirements at § 418.114(c)(3) and (4) and referencing the new requirement at §§ 410.53 and 410.54 respectively. We do not expect any increase in burden for this modification. In addition, we do not expect the changes for this provision to cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

19. RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

We are publishing this RFI in this proposed rule to seek comments from interested parties. There is no impact for this RFI.

20. Basic Health Program Provisions

In this proposed rule, we are proposing to update the requirements for a BHP Blueprint revision. We also propose to allow a State with a BHP to suspend its BHP, if necessary, and provide requirements related to a BHP suspension. We also propose updates to the annual report content and timing, if a BHP is suspended. This proposal includes requirements for accessible notices. Finally, we propose changes related to an individual's appeals rights. We do not anticipate that these provisions would impose any additional regulatory burden.

21. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

We propose in section III.S. to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the Annual Wellness Visit (AWV) by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. We propose that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit. See section II.E. of this proposed rule for additional information on coding, pricing, and additional conditions of payment for the proposed new SDOH Risk Assessment service. We anticipate our proposal to add a SDOH Risk Assessment as an optional, additional element with additional payment within the AWV to result in some additional service utilization, but we also anticipate the additional utilization may be balanced, in part or in whole, by potential long term benefits and savings resulting from a more effective AWV and increased prevention and early detection (allowing for less invasive and more effective treatment). We do not anticipate that the addition of an optional SDOH Risk Assessment to the AWV would result in a significant impact to the Medicare Program.

22. Updates to the Quality Payment Program

In this section, we estimate the overall and incremental impacts of the Quality Payment Program policies proposed in this rule. We estimate participation, final scores, and payment adjustment for clinicians participating through traditional MIPS, MVPs, and the Advanced APMs. We also present the incremental impacts to the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

a. Overall MIPS Modeling Approach and Data Assessment

(1) MIPS Modeling Approach

For this proposed rule we create two MIPS RIA models: a baseline and proposed policy model. Our baseline model includes previously finalized policies that would be in effect for the CY 2024 performance period/2026 MIPS payment year if none of our proposed policies are finalized. Examples of previously finalized policies are an updated methodology for calculating the complex patient bonus, and an increase in the data completeness threshold for quality measures. The proposed policies model builds off the baseline model and incorporates the MIPS policy proposals for the CY 2024 performance period/ 2026 MIPS payment year included in this proposed rule. The aim of the baseline and proposed policy models is to estimate the incremental impacts of the policies in this proposed rule. We used a similar approach in the CY 2023 PFS final rule (87 FR 70199 through 70200).

As discussed in the CY 2023 PFS final rule, our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This modeling approach enables our model to align as much as possible with actual MIPS scoring and minimizes differences between our projections and policy implementation. There are still some limitations to our model due to data limitations and assumptions. These limitations are discussed later in this RIA. The aim of the baseline model is to reflect participation, final scores, and payment adjustments for the upcoming performance period and associated MIPS payment year based on previously finalized policies for the performance period and MIPS and MIPS payment year.

(2) Data Used To Estimate Future MIPS Performance

In the 2023 PFS final rule (87 FR 70200), we discussed our decision to use the submissions data for the CY 2021 performance period to estimate eligibility, final scoring, and payment adjustments supplemented by CY 2019 performance period data to estimate participation and payment adjustments for the sake of estimating the size of the budget neutral pool. To mitigate the potential effect of the PHE on our engagement estimates for the CY 2024 performance period/2026 MIPS payment year, for MIPS eligible clinicians who submitted data for the CY 2019 performance period and did not submit data for the CY 2021 performance period, we assigned their participation status and final score data from the CY 2023 PFS proposed rule baseline model (87 FR 46408). This is because the CY 2023 PFS proposed rule baseline model (87 FR 46408) is based on submissions data for the CY 2019 performance period (hereafter called ''2019 data supplement'').

We indicated that we believed this approach would reflect data that is generally more current while mitigating the impacts of changes in reporting behavior during the PHE on our participation estimates. Although we believe that this is the best data source to accurately model the impact of our proposed policies, the use of data from the CY 2021 performance period supplemented by data from the CY 2019 performance period, has the same limitations as discussed in the 2023 PFS final rule (87 FR 70200). We took a similar approach this year.

The submissions for the CY 2022 performance period were not available in time to assess whether the data for that performance period can be used to predict future performance. For the final rule, we will evaluate whether it is appropriate to use the CY 2022 performance period data and whether adjustments to this RIA model based on factors such as clinician behavior or performance category data availability would need to be made if CY 2022 performance category submissions data were used instead.

b. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years from 2019 through 2025, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs for the applicable QP Performance Period for a year and the corresponding payment year. In payment years 2019 through 2024 these QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the calendar year immediately preceding the payment year. In payment year 2025, QPs will receive a lump-sum APM Incentive Payment equal to 3.5 percent payment of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs but meet a lower threshold to become Partial QPs for the year may elect to report to MIPS and, if they elect to report, will then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year is 0.75 percent, while the update to the PFS CF for services that are furnished by clinicians who do not achieve QP status for a year is 0.25 percent. Thus, eligible clinicians who are QPs for the year will receive differentially higher PFS payment rates than those who are not QPs.

We incorporated this change into our baseline eligibility determination. In addition, the thresholds to achieve QP status beginning in the 2024 QP Performance Period will increase to 75 percent for the payment amount method, and 50 percent for the patient count method. Overall, we estimate that for the 2024 QP Performance Period between 187,000 and 241,000 eligible clinicians will become QPs, and therefore be excluded from MIPS reporting requirements and payment adjustments.

In section VII.E.23.b of this proposed rule, we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2024 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2024 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2024 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track);
- Primary Care First (PCF) Model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).
- Making Care Primary (MCP) tracks 2 and 3.

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see 42 CFR 414.1425(a) for information on the APM Participant Lists and QP determinations) for the 2022 QP performance period third snapshot QP determination date to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2024 QP Performance Period. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

c. Estimated Number of MIPS Eligible Clinicians for the CY 2024 Performance Period/2026 MIPS Payment Year

(1) Clinicians Included in the RIA Baseline and Final Policies Models Prior to Applying the Low-Volume Threshold Exclusion

For this proposed rule, we applied the same assumptions as in the CY 2023 PFS final rule (87 FR 70201 through 70202), unless otherwise noted. In the CY 2023 PFS final rule (87 FR 70202), we explained that we modified some of our assumptions to estimate engagement in MIPS to mitigate the effects of potential non-engagement due to the extreme and uncontrollable circumstances policies related to the PHE.

In the CY 2023 PFS final rule (87 FR 70201), we explained our use of the final reconciled eligibility determination file. This file reconciles eligibility from two determination periods and aligns with the CY 2021 performance period submissions data on which we based this model. In this proposed rule, we again used the final reconciled 2021 eligibility determination file which aligns with CY 2021 performance period submissions data. We did not propose any modifications to MIPS eligibility requirements, therefore the same eligibility assumptions apply to both the baseline and proposed policies models. Our analysis found that there were 1.7 million clinicians who had PFS claims from October 1, 2020 to September 30, 2021. This initial population of clinicians was used to determine eligibility using the processes described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Assumptions for the Low-Volume Threshold Exclusion and Considering the Extreme and Uncontrollable Circumstances Policies Related to COVID–19 PHE

The low-volume threshold policy may be applied at the individual (TIN/NPI) or group (TIN) levels based on how data are submitted to MIPS. Generally, if a clinician or group does not exceed the low-volume threshold criteria then that clinician or group is excluded from participation in MIPS. The low volume threshold uses three criteria: allowed charges, number of Medicare patients who receive covered professional services, and number of services provided. A clinician or group that exceeds at least one, but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby being measured on performance and receiving a MIPS payment adjustment.

We describe below the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.7 million clinicians for the proposed policies model. We applied the same assumptions as in the CY 2023 PFS final rule (87 FR 70201 through 70202) to apply the low-volume threshold and to determine whether clinicians participate in MIPS as a group, virtual group, APM entity, or as individuals. In the CY 2023 PFS final rule (87 FR 70202), we explained our use of the CY 2019 performance period data to update eligibility assumptions to account for the effects of the extreme and uncontrollable circumstances (EUC) policy that was applied due to the PHE. We noted that the use of CY 2021 performance period data alone might overstate the number of clinicians with ''required eligibility'' who do not participate in MIPS due to the PHE under the EUC policy and therefore may not have submitted data. If we assumed in this RIA model, which estimates of CY 2024 performance period/CY 2026 payment year, participation and non-participation to be similar to the CY 2019 performance period, we would likely overstate the number of clinicians receiving a negative payment adjustment. Since these clinicians actually would have received a neutral score under the CY 2021 performance period EUC reweighting policy but would receive a negative payment adjustment in our simulation.

As we noted in section VII.E.22 of this RIA, in order to mitigate the potential effect of the PHE on our engagement estimates for the CY 2024 performance period, for MIPS eligible clinicians who submitted data for the CY 2019 performance period and did not submit data for the CY 2021 performance period, we followed the same process described in the CY 2023 PFS final rule (87 FR 70202) and assigned their participation status and final score data from the CY 2023 PFS proposed rule baseline model (87 FR 46408). This is because the CY 2023 PFS proposed rule baseline model (87 FR 46408) is based on the 2019 data supplement. We believed these clinicians may participate and perform more similarly to the CY 2019 performance period than the CY 2021 performance period during the CY 2024 performance period.

We do not have ability to assess the performance of clinicians reflected in our 2019 data supplement in our model, so we used the same score for this final rule's baseline and proposed policies models. Because we used the same score for the baseline and proposed policies model, we were not able to assess the incremental impact of policies for this group. However, we believe making this adjustment is valuable because it helps mitigate the potential effect of overestimating the number of clinicians eligible for, and participating in MIPS, versus non-participants, which in turn would affect our estimation of the MIPS redistribution payment and the size of the budget neutral pool.

For our RIA model, we established the ''required eligibility'' category, which means the clinician exceeds the low-volume threshold in all 3 criteria and is subject to a payment adjustment is separated into three buckets this year: (1) ''Clinicians who Report''; (2) ''Did not report in 2021, but did report in 2019''; and (3) ''Did not report in either 2021 or 2019.'' We have done this so that we can isolate both the effects of our proposed policies, which are modeled using 2021 data, the effect of the 2019 data supplement, and model the population of clinicians who did not engage in either year. The year refers to which population of data we used (that is, the 2021 population of clinicians or the 2019 supplement).

(a) MIPS Eligibility Estimates

Table 117 summarizes our eligibility estimates for the proposed policies model after applying our assumptions discussed previously.

We estimate approximately 122,183 MIPS eligible clinicians have the required eligibility criteria and submitted data for at least one performance category in MIPS for the CY 2019 and 2021 performance periods, 9,906 MIPS eligible clinicians who did not engage in MIPS based on 2021 performance period MIPS data but did engage based on 2019 performance period MIPS data, and 14,289 MIPS eligible clinicians counted in our model as ''did not submit in data to MIPS for the CY 2019 or CY 2021 performance period.'' These are clinicians who did not submit data to MIPS for the CY 2019 or CY 2021 performance periods, or did not submit data to MIPS for the CY 2021 performance period and do not have CY 2019 performance period data.

We estimate approximately 664,562 MIPS eligible clinicians as having ''group eligibility'' in Table 117. ''Group eligibility'' means that these clinicians belong to a group that exceeds the low-volume threshold. If they were not associated with the group submission, these clinicians will not be eligible for MIPS.

Finally, we estimate about 9,107 clinicians will be eligible for MIPS and participate through ''opt-in eligibility''

through the ''opt-in'' policy. We updated our opt-in policy to reflect that a clinician can elect to opt-in into MIPS and will be scored, even if they do not submit data to MIPS.

We estimate a total MIPS eligible clinician population of approximately 1,741,607 with $9 billion PFS allowed charges estimated to be included in the CY 2024 performance period/2026 MIPS payment year.

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TABLE 117: Description of MIPS Eligibility Status for CY 2023 Performance Period/2025 MIPS Payment Year Using the CY 2023 PFS Final Rule Assumptions**

		CY 2024 PFS Proposed Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians ***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*** **
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS *	122,183	$34,134
	Did not Report in 2021 but Reported in 2019	9,906	$2,963
	Did not Report in 2021 and did not Report 2019 (or did not have data in 2019)*	14,289	$4,261
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	664,562	$17,533
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	9,107	$473
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**820,047**	**$59,363**
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	185,342	$6,211
	Group Eligible; Did not Report	294,729	$6,701
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	123,231	$834
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	75,836	$4,442
Qualified Participant (QP)***	Not applicable	242,422	$13,502
Total Number of Clinicians Not MIPS Eligible		**921,560**	**$31,690**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		**1,741,607**	**$91,053**

* Participation excludes facility-based clinicians who do not have scores in the 2021 MIPS submission data.
** Allowed charges estimated in 2021 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.
*** Our QP estimate differs from that reported in section VII.E.23.b) of this proposed rule because we 2021 data and a different simulation methodology

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Furthermore, we estimate there will be approximately 185,342 clinicians who are not MIPS eligible, but could be if the clinician or their group elects to

opt-in. We describe this group as ''Potentially MIPS eligible'' in Table 117. These potentially MIPS clinicians would all be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group, or clinicians in a group that does not submit are eligible to opt-into MIPS individually and choose to do so. We do not expect that every potentially MIPS eligible clinician will elect to submit data to MIPS. We estimate another 294,729 clinicians would be eligible for participation as a group but do not report data. These assumptions are important because they quantify the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate the MIPS eligible clinician population could be as high as 1,300,118 clinicians. Finally, we estimate approximately 123,231 clinicians will not be MIPS eligible because they and their group are below the low-volume threshold on all three criteria and another approximately 318,258 will not be MIPS eligible for other reasons, including 242,422 clinicians with QP status.

Eligibility among many clinicians is contingent on submission to MIPS as a group or election to opt-in, therefore we will not know the number of MIPS eligible clinicians who submit until the submission period for the CY 2023 performance period is closed. For the remaining analysis, we use the estimated population of 820,047 MIPS eligible clinicians described above.

c. Estimated Impacts on Payments to MIPS Eligible Clinicians for the CY 2023 Performance Period/2025 MIPS Payment Year

(1) Summary of Approach for MIPS Value Pathways (MVPs) and Traditional MIPS

In this proposed rule, we present several proposals which impact the measures and activities, the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.E.23.d.(3) of this RIA as we describe our methodology to estimate MIPS payments for the CY 2024 performance period/2026 MIPS payment year. We then present the impact of the overall proposed policies in the CY 2024 performance period/2026 MIPS payment year and then compare select metrics to the baseline model, which only incorporates previously finalized policies for the CY 2024 performance period/2026 MIPS payment year. By comparing the baseline model to the proposed policies model, we are able to estimate the incremental impact of the proposed policies for the CY 2024 performance period/2026 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is calculated based on the clinician's performance on measures and activities under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate as an individual, group, virtual group, APM Entity, clinicians participating in MIPS through the APM Performance Pathway (APP) or through an MVP in the four MIPS performance categories. MIPS APM participants can participate in the APP as an individual, group, virtual group, APM Entity and are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability.

The average percentage change in total revenues that clinicians earn is less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; MIPS does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that will not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact for MIPS Value Pathways

In the CY 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MVPs beginning in the CY 2023 performance period/2025 MIPS payment year. In this RIA, we take a similar approach to modeling MVP participation and scoring as described in the CY 2022 PFS final rule (87 FR 70204), incorporating changes to our proposed policies model as described below.

(a) MVP Participant Assumptions

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup, or APM entity) to register prior to submitting an MVP. As we do not yet have information on who will register, we assume for purposes of this model, that MVP Participants are MIPS eligible individual clinicians or groups that currently submit at least four quality measures that are in an MVP. For these MVP Participants, we calculate both an MVP and a traditional MIPS score and take the highest score consistent with the existing scoring hierarchy which was finalized in the CY 2023 PFS final rule (86 FR 65537). For the baseline model, we used the quality measures finalized for MVPs in the CY 2023 PFS final rule Appendix 3: MVP Inventory.

In section IV.A.4.b and Appendix 3 of this proposed rule, we propose modifications to the 12 existing MVPs finalized in the CY 2022 PFS final rule (86 FR 65998 through 66031) and CY 2023 PFS final rule (87 FR 70037) and the consolidation of the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care.

In section IV.A.4.a of this proposed rule, we are proposing the inclusion of 5 new MVPs

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disease Including Hepatitis C and HIV;
- Quality Care in Mental Health and Substance Use Disorder;
- Quality Care for Ear, Nose, and Throat (ENT); and
- Rehabilitative Support for Musculoskeletal Care

For the proposed policies model, we incorporate the quality measure revisions for the existing MVPs and use the quality measures to model scores for the new MVPs in Appendix 3 of this proposed rule.

Our MVP Participant assumptions have limitations: we are not incorporating subgroups due to a lack of data, not all of the assumed participants may elect to register for an MVP, and we may have additional clinicians or groups register for an MVP. However, we believe this is a reasonable approach to simulate the impact of MVPs and we sought comment on this assumption, but did not receive any feedback.

(b) MVP Scoring Methods and Assumptions

We simulate an MVP score using the same data sources as we did for traditional MIPS. We scored according to § 414.1365(d) and § 414.1365(e) using the MVP reporting requirements listed in § 414.1365(c) with one exception. We did not restrict the improvement activities to the activities listed in the MVP inventory. We believed this would lower our estimated MVP score as clinicians and groups were not required to select from a limited inventory in the CY 2021 performance period (upon which our model is based). Therefore, we scored any improvement activities the MVP Participants submitted in 2021

as if those improvement activities are in the MVP inventory.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the proposed policies on MIPS eligible clinicians, we generally used the CY 2021 performance period's submissions data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories. As discussed in section VII.E.23.a.(2) of this proposed rule, we supplemented with 2019 data supplement.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2024 performance period/2026 MIPS payment year for the baseline and proposed policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, where each are described in detail in the following sections.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a methodology like the one described in the CY 2023 PFS final rule (87 FR 70205) for the baseline and proposed policies RIA models for the CY 2024 performance period/2026 MIPS payment year.

To create the baseline policies RIA model, which does not reflect the policies proposed in this rule, we made the following modifications to the CY 2023 PFS final rule final policies model to reflect the previously finalized quality performance category policies for the CY 2024 performance period/2026 MIPS payment year:

- As discussed in the CY 2023 PFS final rule (87 FR 70049), we increased the data completeness criteria threshold to at least 75 percent for CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years.

For the proposed policies model, we did not implement any changes to the quality performance category relative to the baseline model because we use 2021 data and cannot simulate the addition of new measures.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2023 PFS final rule (87 FR 70205) for the baseline and the proposed policies RIA models. For this proposed rule, the baseline policies RIA model included the same method used for the final policies RIA model in the CY 2023 PFS final rule (87 FR 70205). Due to technical limitations, we did not model cost improvement scoring in the baseline policies RIA model.

The proposed policies RIA model incorporated and implemented the following changes:

In section IV.A.4.f.(2).(a) of this proposed rule, we proposed 5 new episode-based cost measures.

- In section IV.A.4.g.(1).(c) of this proposed rule, we proposed to:

++ Determine cost improvement scoring at the category level;

++ Modify how to calculate cost improvement scoring and remove statistical significance requirement; and

++ Set the maximum improvement scoring to 1 percentage point, beginning in CY 2023 performance period/2025 MIPS payment year.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

A limitation of using data from the CY 2021 performance period is that we are not able to estimate facility-based scores because there are no Hospital Value-Based Purchasing total performance scores calculated for the performance period due the COVID–19 PHE. However, for clinicians who did not participate in MIPS during the CY 2021 performance period, we did use the 2019 data supplement to identify final scores based on the CY 2019 performance period submission and these scores include facility-based scores.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated the baseline Promoting Interoperability performance category score by using the same methodology that we used in the CY 2023 PFS final rule (87 FR 70206) final policies. We incorporated the final policies model from that rule into our baseline model. In section IV.A.4.F.(4)(f) of this proposed rule, we proposed to continue reweighting clinical social workers. This is incorporated into our proposed policies model. We did not incorporate changes to the performance period or measure level changes because we are not able to model this using data for the CY 2021 performance period.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline and proposed policies model we used the same method to estimate the improvement activities performance category score as described in the CY 2023 PFS final rule (87 FR 70206).

(f) Methodology To Estimate the Complex Patient Bonus Points

For the baseline and proposed policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(g) Methodology To Estimate the Final Score

We did not propose any changes for how we calculated the MIPS final score. Our baseline and proposed policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For the baseline policies RIA model, we applied the performance category weights and redistribution weights finalized in the CY 2022 PFS final rule (86 FR 65519 through 65524).

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

(h) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and proposed policies RIA models, we applied the hierarchy as finalized in the CY 2022 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we applied the performance threshold of 75 points finalized in the CY 2023 PFS final rule (87 FR 70097). In section IV.A.4.h.(2) of this proposed rule, we are proposing a

performance threshold of 82 points for the CY 2024 performance period/2026 MIPS payment year, which we incorporated into our proposed policies model. For both the baseline and proposed policies models, we used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Impact of Payments

We noticed minimal changes to the mean and median final score between our baseline and proposed policies models. In our baseline model, the mean and median final scores are 73.26 and 79.99 points, respectively. In the proposed policies model, the mean final score is 73.52 and the median final score is 80.53. Many clinicians have scores clustered near the proposed performance threshold of 82 points. For instance, 51% of clinicians have a final score between 80 and 100 points and 63.28% of clinicians have final score between 75 and 100 points. Because so many clinicians have final scores near our proposed performance threshold, a small change in actual final scores relative to our model would significantly impact the number of clinicians with a positive, neutral, or negative adjustment.

Our proposed policies are expected to increase the number of clinicians receiving a negative adjustment from 36.75 percent of eligible clinicians to 54.31 percent of eligible clinicians, but decrease the average negative adjustment from −2.89 percent to −2.40 percent. This is because the increased performance threshold will cause many clinicians who previously scored slightly above the performance threshold to now score slightly below the performance threshold, shifting their expected payment from a small positive adjustment to a small negative adjustment.

Among MIPS eligible clinicians who reported data, 35.38 percent receive a negative adjustment in our baseline model compared to 52.24 percent in the proposed policies model. Because many clinicians' scores are close to the performance threshold, the payment adjustments for these clinicians are fairly small and many negative adjustments are much lower in magnitude than the statutory maximum negative adjustment of 9 percent. In our proposed policies model, we project the maximum negative payment adjustment of negative 9 percent for clinicians with a score of 20 points or below compared to a score of 18 in our baseline model.

In our baseline model, 2.13 percent of MIPS eligible clinicians and 1.41 percent of clinicians who report clinicians receive the max negative adjustment. In our proposed rule model, 1.99 percent of MIPS eligible clinicians and 1.19 percent of clinicians who report data receive the max negative adjustment. This is because, while the range of scores subject to the maximum negative adjustment increases slightly (from 18 to 20 points), slightly fewer clinicians in our proposed policies model have a final score below 20 points compared to the baseline model.

The increase in the number of clinicians receiving a negative score will contribute to an increase in the size of the budgetary dollars available, as a result of the budget neutral nature of the program. In the baseline model, we anticipate redistributing $7.4 million and, in the proposed policies model we anticipate, redistributing $8.9 million as a result of budget neutrality.

Because of this increase in the size of the budget neutral pool, the size of our positive payment adjustments increases. In our baseline model, the average positive payment adjustment is 1.99 percent among MIPS eligible clinicians. In the CY 2024 performance period/2026 MIPS payment year proposed policies model, the average positive payment adjustment is 3.35 percent among MIPS eligible clinicians. The maximum positive payment adjustment increased from 4.60 percent in the baseline model to 8.82 percent in the proposed rule model.

We want to highlight that we are primarily using submissions data for the CY 2021 performance period to simulate a final score for the CY 2024 performance period/2026 MIPS payment year, and it is likely that there will be changes that we cannot account for at this time. It should also be noted that the estimated number of clinicians who do not submit data to MIPS may be an overestimate of non-engagement in MIPS for the CY 2023 performance period/2025 MIPS payment year. This is because the PHE may have resulted in fewer clinicians submitting data to MIPS or more clinicians electing to apply for the extreme and uncontrollable circumstances policies due to the PHE for the CY 2019 and CY 2021 performance periods. Therefore, engagement levels in MIPS for the CY 2024 performance period/2026 MIPS payment year may differ from these reported estimates. We also note this participation data is generally based off participation for the CY 2021 performance period/2023 MIPS payment year, which is associated with a performance threshold of 60 points.

TABLE 118: Estimated Proportion of Eligible Clinicians with a Positive or Neutral and a Negative Payment Adjustment CY 2024 Performance Period/2026 MIPS Payment year by Practice Size

Practice Size*	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline		
1) Solo	46.94%	53.05%
2) 2-15	53.76%	46.23%
3) 16-99	54.55%	45.44%
4) 100+	68.68%	31.31%
Overall	63.24%	36.75%
Proposed Policies Model		
1) Solo	35.39%	64.60%
2) 2-15	39.81%	60.18%
3) 16-99	37.44%	62.55%
4) 100+	50.15%	49.84%
Overall	45.68%	54.31%

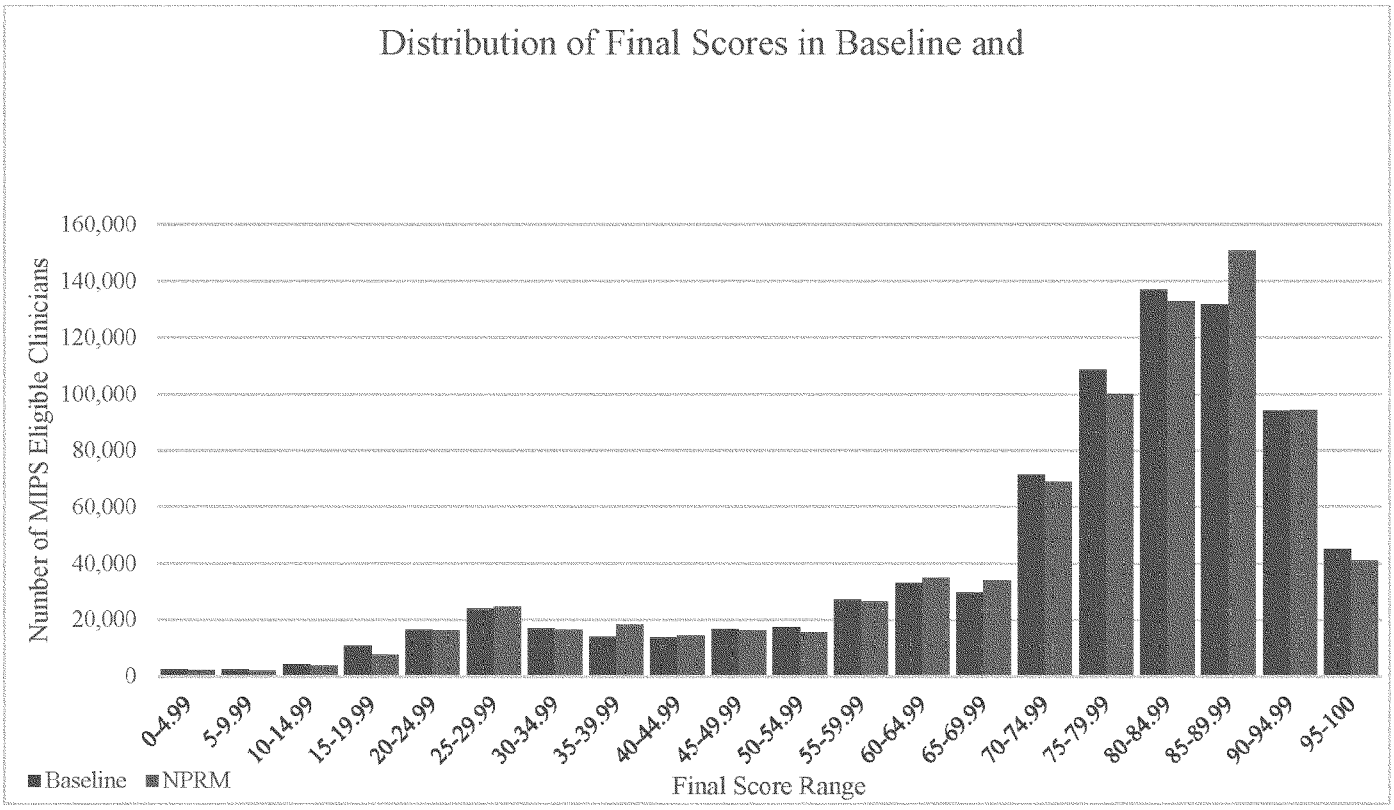
TABLE 119: Average and Maximum Positive Adjustments for Eligible Clinicians in the CY 2024 Performance Period /2026 MIPS Payment Year By Practice Size

Practice Size	Number of MIPS Eligible Clinicians	Average Positive Adjustment	Maximum Positive Payment Adjustment
Baseline			
Solo (1)	7,059	2.49%	4.60%
Small (2-15)	50,559	2.40%	4.60%
Medium (16-99)	104,742	2.01%	4.60%
Large (>99)	353,970	1.92%	4.60%
Overall	516,330	1.99%	4.60%
CY 2024 PFS Proposed Rule			
Solo (1)	5,322	4.62%	8.82%
Small (2-15)	37,503	4.10%	8.82%
Medium (16-99)	72,935	3.38%	8.82%
Large (>99)	258,849	3.21%	8.82%
Overall	374,609	3.35%	8.82%

TABLE 120: Average and Maximum Negative Adjustments for Eligible Clinicians in the CY 2024 Performance Period /2026 MIPS Payment Year By Practice Size

Practice Size	Number of MIPS Eligible Clinicians	Average Negative Adjustment	Maximum Negative Payment Adjustment
Baseline			
Solo (1)	7,977	-4.32%	-9.00%
Small (2-15)	43,476	-4.17%	-9.00%
Medium (16-99)	87,250	-2.95%	-9.00%
Large (>99)	161,379	-2.44%	-9.00%
Overall	300,082	-2.89%	
CY 2024 PFS Proposed Rule			
Solo (1)	9,714	-3.93%	-9.00%
Small (2-15)	56,683	-3.59%	-9.00%
Medium (16-99)	121,819	-2.54%	-9.00%
Large (>99)	257,222	-2.01%	-9.00%
Overall	445,438	-2.40%	-9.00%

FIGURE 4: Distribution of Final Scores in the Baseline and Proposed Policies Model



e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting the payment adjustments, we are proposing several policies that have an impact on burden in the CY 2024 performance period/2026 MIPS payment year. In section V.B.11. of this proposed rule, we outline estimates of the costs of data collection that includes both the effect of proposed policy updates and adjustments due to the use of updated data sources. For each proposed provision included in this proposed rule which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 121. We also provide proposed additional burden discussions that we are not able to quantify.

TABLE 121: Incremental Burden from Associated Proposed Policies

Burden Description and associated finalized provisions	Burden Hours	Burden Dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2023 PFS final rule into the CY 2024 performance period/2026 MIPS payment year (as discussed in section V.B11. of this proposed rule).	630,570	$71,317,983
Burden change for MVP registration ICR due to the provision of additional MVPs (as discussed in section V.B.11e.(7)(a) of this proposed rule). *	+321	+$33,192
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(4) of this proposed rule). *	-4,743	-$530,492
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(5) of this proposed rule). *	-3,697	-$423,093
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(6) of this proposed rule). *	-4,344	-$503,665
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (as discussed in section V.B.11.e.(7)(a)(iii) of this proposed rule). *	+8,461	+$964,505
Total change in burden due to policy for CY 2024	-4,002	-$459,553
Total burden set forth in the CY 2024 PFS proposed rule	626,568	$70,858,430

* The total change in burden due to this provision includes an increase in burden due to an anticipated increase in the number of respondents that will participate in MVP reporting based on the proposed addition of new MVPs. Therefore, there will be a decrease in burden in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRS due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as a MVP participant. Total change in burden also includes the increase in submission burden due to the increase in the number of respondents for "MVP registration." See section V.B.11 of this proposed rule.

(2) Additional Impacts to Clinicians

(a) Impact on Third Party Intermediaries

In section IV.A.4.k of this rule, we are proposing to: (1) add requirements for third party intermediaries to obtain documentation; (2) add requirements for third party intermediaries to submit data in the form and manner specified by CMS; (3) specify the use of a simplified self-nomination process for existing QCDRs and qualified registries; (4) add requirements for QCDRs and qualified registries to provide measure numbers and identifiers for performance categories; (5) Add a requirement for QCDRs and qualified registries to attest that information on the qualified posting is correct; (6) Modify requirements for QCDRs and qualified registries to support MVP reporting; (7) Specify requirements for a transition plan for QCDRs and qualified registries; (8) Specify requirements for data validation execution reports; (9) Add additional criteria for rejecting QCDR measures; (10) Add a requirement for QCDR measure specifications to be displayed throughout the performance period and data submission period; (10) eliminate the Health IT vendor category; (11) Add failure to maintain updated contact information as criteria for remedial action; (12) Revise corrective action plan requirements; (13) Specify the process for publicly posting remedial action; and (14) Specify the criteria for audits. Due to the technical nature of these proposed changes, we are unable to quantify the burden for third party intermediaries during the CY 2024 performance period/2026 MIPS payment year. We refer readers to section V.B.11.c of this rule for additional information on proposed changes to the third party intermediary requirements.

(b) Compare Tools: Public Reporting

In section IV.A.4. of this rule, we are proposing to update our policy for identifying clinicians furnishing telehealth services, such that we remain current with CMS coding changes, without proposing and finalizing such coding changes via rulemaking. Specifically, instead of only using place of service (POS) codes 02, 10, or modifier 95 to identify telehealth services furnished for the telehealth indicator, we would use the most recent codes at the time the data are refreshed. We are proposing that at the time of such a data refresh we would publish the details of which codes are used for the telehealth indicator through education and outreach, such as via a fact sheet, listserv, or information posted on the Care Compare: Doctors and Clinicians Initiative page, available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/care-compare-dac-*

initiative. We are proposing to revise the policy to publicly report a subset of the Medicare public use file (PUF) on the Provider Data Catalog (PDC) to instead provide a single downloadable dataset reflecting including the procedure utilization data that would appear on clinician profile pages. We are proposing to modify the existing policy such that, in addition to the two previously finalized sources (Restructured BETOS categorization system and code sources used in MIPS), we may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists. If we develop new procedure categories for publicly reporting utilization data on clinician profile pages, we are proposing to engage subject matter experts and interested parties through periodic requests for feedback using methods outside of rulemaking, such as but not limited to listserv emails, listening sessions, and focus groups, to solicit feedback on bespoke procedure categories planned for future releases of utilization data, as appropriate and technically feasible. We are also proposing to publicly report aggregated counts of procedures performed by providers based on Medicare Advantage (MA) encounter data (also known as MA risk adjustment data) in addition to Medicare fee-for-service (FFS) utilization data counts; as part of this proposal, we are proposing to amend 42 CFR 422.310(f) (the regulation that addresses permissible uses and releases of MA risk adjustment data) to permit use of MA encounter data in developing the data posted on the Care Compare website and release of the MA encounter data as part of the data set that will be downloadable from the Care Compare website more quickly than the regulation would currently permit releases of MA encounter data. While the Compare tool provisions do not increase the burden of collections, we note that the PRA package may require relevant modification to reflect the Compare tool's new uses and public display. We refer readers to section IV.A.I of this rule for additional information on the proposed changes to public reporting on Compare tools.

(c) Data Completeness Criteria for the Quality Measures, Excluding the Medicare CQMs

In section IV.A.5.a.(1) of this proposed rule, we are proposing to maintain the data completeness criteria threshold at 75 percent for the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years, and increase the data completeness criteria threshold by 5 percent from 75 percent to 80 percent for the CY 2027 performance period/2029 MIPS payment year. We believe that the proposed policy to maintain the threshold for data completeness at 75 percent for the CY 2025 and 2026 performance periods/ 2027 and 2028 MIPS payment years is consistent with the existing data completeness criteria and therefore, would not result in additional burden to the applicable interested parties. We assume that the proposed increase in data completeness criteria threshold from 75 to 80 percent for the CY 2027 performance period/2029 MIPS payment year would not result in substantive burden to the applicable interested parties We believe that the increase in data completeness criteria threshold would reduce burden for clinicians using EHRs and eCQMs as the collection of eCQM data within the EHR can allow eligible clinicians to report on 100 percent of the eligible population with data in the EHR for a measure. Additionally, we recognize that individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities that continue to utilize other means of data collection for MIPS CQMs, including the collection of MIPS CQM data reported by registries and/or QCDRs, would need have the logic code of their EHRs to be updated to account for the increased data completeness criteria threshold. We believe that increasing the data completeness criteria threshold would not pose a substantial burden to MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities, unless they are manually extracting and reporting quality data. We refer readers to section IV.A.4.f.(1)(d) of this rule for additional information on proposed changes to the data completeness threshold criteria.

(d) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.4.f.(3).(b)(ii) of this proposed rule, we are proposing changes to the improvement activities Inventory for the CY 2024 performance period/2026 MIPS payment year and future years as follows: adding five new improvement activities; modifying one existing improvement activity; and removing three previously adopted improvement activities. We refer readers to Appendix 2: Improvement Activities of this proposed rule for further details. We do not believe these proposed changes to the improvement activities inventory would significantly impact time or financial burden on interested parties because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect these proposed changes to the improvement activities inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate most clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies in this proposed rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the CY 2024 performance period/2026 MIPS payment year. We refer readers to section IV.A.4.f.(3)(b) of this rule for additional information on proposed changes to the improvement activities Inventory.

(3) Update to CEHRT Definition for the Medicare Promoting Interoperability Program and the Quality Payment Program

In section III.R of this proposed rule, we propose to update the definitions of CEHRT for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs and for the MIPS Promoting Interoperability performance category. Under this proposal, we would revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at § 495.4, and for the Quality Payment Program at § 414.1305. Specifically, we propose to add a reference to the ''Base EHR Definition'' where the regulatory text refers to the ''2015 Edition Base EHR definition,'' remove ''2015 Edition'' where we reference ''2015 Edition health IT certification criteria,'' and add a cross-reference to health IT certification criteria at § 170.315. We also propose to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria at § 170.315, ''as adopted and updated by ONC.'' We believe that these revisions to the CEHRT definitions, if finalized, would ensure that updates to the definition at § 170.102 and updates to applicable health IT certification criteria in § 170.315 would be incorporated into CEHRT definitions, without requiring additional regulatory action by CMS. Finally, we note that while this proposal is consistent with the approach in ONC's HTI–1 proposed rule (88 FR 23746 through 23917), we do not believe that ONC must finalize their

proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT. These changes would not impact EHR requirements in the CY 2024 EHR reporting period or the CY 2024 performance period, and therefore we predict that it would have no impact on clinicians.

f. Assumptions & Limitations

In section VII.E.23.a.(2) of this rule, we outline several limitations in using 2021 submissions data for estimating performance in the CY 2024 performance period/CY 2026 payment year. In addition, because many scores are clustered between the prior performance threshold of 75 points and the proposed threshold of 82 points, minor variations in actual clinicians final scores relative to our estimations could have significant impacts on the proportion of clinicians receiving a positive or negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2021 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2023 performance period/2025 MIPS payment year. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policies.

In addition to the limitations described throughout the methodology sections, to the extent that there are year-to-year changes in the data submission, volume, and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 118.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we proposed to exercise agency discretion, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we present above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered Related to the O/O E/M Visit Inherent Complexity Add-On Separate Payment

We considered alternatives to our proposed policy to make separate payment for the O/O E/M visit inherent complexity add-on code, including proposing to maintain our current utilization assumptions. Maintaining our current utilization assumption as finalized in CY 2021 would result in an estimated impact or change to the CF of −3.2 percent (Table 122). However, maintaining the CY 2021 policy utilization assumption would not reflect our proposed limitation on billing of the O/O E/M visit inherent complexity add-on code for services billed with modifier 25 which is used to indicate that the service is billed on the same day as a minor procedure or another E/M visit. It seems likely that visits reported with payment modifiers have resources that are sufficiently distinct from stand-alone office/outpatient E/M visits (85 FR 84571). Interested parties that are unlikely to bill for the O/O E/M visit inherent complexity add-on code have continued to express concerns about potential associated reductions to the CF and redistributive impacts among specialties. Our proposal to better target the add-on code would at least partially allay those concerns. Under our proposed utilization assumption for CY 2024, we estimate the effect of making separate payment for the O/O E/M visit complexity add-on code to be −2.0 percent.

TABLE 122: Estimated Conversion Factor Effect Attributable to the Inherent Complexity Add-on Code

As finalized for CY 2021	-3.2%
As proposed for CY 2024	-2.0%

We also considered proposing not to make separate payment for the O/O E/M visit inherent complexity add-on code for CY 2024, continuing to consider the utilization data, and seeking comment on not making separate payment until CY 2025 instead of CY 2024. While doing so would reduce the change to the CF and the redistributive impacts among specialties our concerns about capturing the work associated with visits that are part of ongoing, comprehensive primary care and/or care management for patients having a single, serious, or complex chronic condition would remain present. We believe separate payment for the O/O E/M visit inherent complexity add-on code will improve accuracy in payment for resource costs inherent to primary care and other medical care services that are part of ongoing care for a patient's single, serious or complex condition in the office setting. This would be particularly important for people without access to such care. We also believe that utilization of high-value preventive services, and promotion of healthy behaviors leveraged by these kinds of longitudinal patient relationships could result in positive patient outcomes and positive health equity impacts. Primary care practitioners and other practitioners who rely heavily on these visit codes and would use the add-on code would likely raise strong objections if CMS did not propose to make separate payment for a code that is intended to address long-standing distortions in PFS payment that CMS has repeatedly acknowledged through notice and comment rulemaking.

2. Alternatives to Provider Enrollment Provisions

We did not consider alternatives to our proposed provider enrollment provisions. We believe these changes are necessary to help ensure that payments are made only to qualified providers and suppliers and/or to increase the efficiency of the Medicare and Medicaid provider enrollment processes.

3. Alternatives Considered Medicare Diabetes Prevention Program

No alternatives were considered. The MDPP flexibilities resulting from the PHE for COVID–19 lasted over 3 years of the initial 5 years of the expanded model. During this time, supplier and beneficiary expectations changed, resulting in the synchronous virtual delivery of healthcare services becoming normalized. Requiring the MDPP expanded model to return to primarily

in-person services following over 3 years of synchronous virtual delivery may have an extremely negative impact for both MDPP suppliers and beneficiaries, which could threaten the success of the entire expanded model.

4. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran separate proposed policies RIA models based on the actual mean for the CY 2019 performance period/2021 MIPS payment year with a performance threshold of 86. This model has the same mean and median final score as our proposed policies RIA model since the performance threshold does not change the final score. In our analysis of the alternative performance threshold of 86, 67.20 percent of MIPS eligible clinicians who submitted data would receive a negative payment adjustment.

We also report the findings for the baseline RIA model which describes the impact for the CY 2024 performance period/2026 MIPS payment year if this proposal is not finalized including previous polices including a performance threshold of 75. The baseline RIA model has a mean final score of 73.26 and median final score of 79.99. We estimate that $741 million would be redistributed based on the budget neutrality requirement. There would be a maximum payment adjustment of 4.60. In addition, 36.75 percent of MIPS eligible clinicians would receive a negative payment adjustment.

G. Impact on Beneficiaries

1. Medicare Shared Savings Program Provisions

As noted previously in this proposed rule, the proposal to cap an ACO's regional service area risk score growth is expected to increase the incentive for ACOs to participate in regions with high risk score growth, improving the incentive for ACOs to join and/or sustain participation when serving regions with increasingly medically complex beneficiaries. Similarly, the proposal to use a uniform approach to calculating both BY and PY prospective HCC risk scores using the same CMS–HCC risk adjustment model(s) is anticipated to increase participation (and reduce the potential for disenrollment) particularly from ACOs serving greater proportions of complex beneficiaries exhibiting high risk scores. The proposal to mitigate the impact of the negative regional adjustments on benchmarks is expected to increase participation from ACOs serving up to 500,000 new assigned beneficiaries per year. The proposal to revise the definition of an assignable beneficiary is expected to allow more than 760,000 additional beneficiaries to be included in the population of assignable beneficiaries, many of whom would be eligible to be assigned to ACOs. In total these proposals are expected to increase participation in the Shared Savings Program over the 2024–2033 period by roughly 10 to 20 percent.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in the MIPS. In addition, ACOs continued to have higher mean performance than their MIPS Group counterparts on all 10 of the CMS Web Interface measures for PY 2021. This includes higher performance for quality measures related to diabetes and blood pressure control; depression screening and depression remission rates; breast, colorectal and falls risk screening rates; and flu vaccination, tobacco screening and smoking cessation, and statin therapy for the treatment and prevention of cardiovascular disease.

Increased participation in the Shared Savings Program will extend ACO care coordination and quality improvement to segments of the beneficiary population that potentially have more to benefit from care management.

2. Quality Payment Program

There are several changes in this proposed rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate the proposed policies in this proposed rule will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the proposed new quality measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

3. Medicare Diabetes Prevention Program

The proposed changes would have a positive impact on eligible MDPP beneficiaries, as it increases the accessibility of MDPP, particularly among beneficiaries residing in rural and underserved areas of the US, where access to a supplier offering in-person Set of MDPP services may not exist or be geographically feasible.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's proposed rule will be the number of reviewers of last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons we believe that the number of commenters will be a fair estimate of the number of reviewers of last year's proposed rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $984.48 (8.0 hours × $123.06). Therefore, we estimated that the total cost of reviewing this regulation is 22,978,748 ($984.48 ×

23,341 reviewers on last year's proposed rule).

As for the Medicare Diabetes Prevention Program, given that we tried to align this rule as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rule impacts only enrolled MDPP suppliers and eligible beneficiaries who have started the MDPP program or are interested in enrolling in MDPP.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 123 through 125 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2023 to CY 2024 based on the FY 2024 President's Budget baseline.

TABLE 123: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2024 Annualized Monetized Transfers	Estimated decrease in expenditures of $2.4 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 124: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2024 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.6billion
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 125: Accounting Statement for Proposals for Medicare Shared Savings Program (CYs 2024-2033)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	-15 million	-171 million	174 million	Tables 109 through 112
Annualized monetized: Discount rate: 3%	-25 million	-189 million	172 million	

Notes: Negative values reflect reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects will be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 5, 2023.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Health facilities, Health professions, Medicare Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations,

Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare Reporting and recordkeeping requirements.

42 CFR Part 600

Administrative practice and procedure, Health care, Health insurance, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.800 is amended by adding paragraph (d) to read as follows:

§ 405.800 Appeals of CMS or a CMS contractor.

* * * * *

(d) *Scope of supplier.* For purposes of this subpart, the term ''supplier'' includes all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202 of this chapter.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

■ 3. Section 405.2401 is amended by adding the definition of ''Marriage and family therapist (MFT)'' and ''Mental health counselor (MHC)'' to paragraph (b) in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Marriage and family therapist (MFT) means an individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter.

* * * * *

Mental health counselor (MHC) means an individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

* * * * *

■ 4. Section 405.2411 is amended by revising paragraphs (a)(4), (a)(6), and (b)(2) to read as follows:

§ 405.2411 Scope of benefits.

(a) * * *

(4) Services and supplies furnished as incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(6) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services as specified in § 405.2450.

(b) * * *

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed or under contract with the RHC or FQHC at the time the services are furnished;

* * * * *

■ 5. Section 405.2413 is amended by revising paragraph (a)(5) to read as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care Model, and behavioral health services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

* * * * *

■ 6. Section 405.2415 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(3), and (a)(5) and

■ b. Adding paragraphs (b)(6) and (7).

The revisions and additions read as follows:

§ 405.2415 Incident to services and direct supervision.

(a) Services and supplies incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor are payable under this subpart if the service or supply is all of the following:

* * * * *

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care model, and behavioral health services can be

furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) * * *

(6) Marriage and family therapist.

(7) Mental health counselor.

* * * * *

■ 7. Section 405.2446 is amended by revising paragraphs (b)(5) and (6) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) * * *

(5) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services specified in § 405.2450.

(6) Services and supplies furnished as incident to the services of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor, as specified in § 405.2452.

* * * * *

■ 8. Section § 405.2448 is amended by revising paragraphs (a)(2) introductory text and (a)(2)(i) to read as follows:

§ 405.2448 Preventive primary services.

(a) * * *

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed by or under contract with the FQHC.

(i) By a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor; or

* * * * *

■ 9. Section 405.2450 is amended by revising the section heading and paragraphs (a) introductory text, (a)(2), (a)(3), and (c) to read as follows:

§ 405.2450 Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) For clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor professional services to be payable under this subpart, the services must be—

* * * * *

(2) Of a type that the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

* * * * *

(c) The services of clinical psychologists, clinical social workers, marriage and family therapist, or mental health counselors are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

■ 10. Section 405.2452 is amended by revising the section heading, and paragraphs (a) introductory text, (a)(3), (a)(5) and (b) to read as follows:

§ 405.2452 Services and supplies incident to clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) Services and supplies incident to a clinical psychologist's, clinical social worker's, marriage and family therapist's, and mental health counselor's services are reimbursable under this subpart if the service or supply is—

* * * * *

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor;

* * * * *

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor is permitted to supervise such services under the written policies governing the FQHC.

■ 11. Section 405.2463 is amended by—

■ a. Adding paragraphs (a)(1)(i)(I) and (a)(1)(i)(J);

■ b. Revising paragraph (b)(3) introductory text;

■ c. Redesignating paragraph (b)(3)(iii) as paragraph (b)(3)(v); and

■ d. Adding paragraphs (b)(3)(iii) and (b)(3)(iv).

§ 405.2463 What constitutes a visit.

(a) * * *

(1) * * *

(i) * * *

(I) Marriage and family therapist.

(J) Mental health counselor.

* * * * *

(b) * * *

(3) A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2025, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

(iii) Marriage and family therapist.

(iv) Mental health counselor.

* * * * *

■ 12. Section 405.2464 is amended by revising paragraph (c) to read as follows:

* * * * *

(c) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician fee schedule national non-facility payment rate. For care management services furnished between January 1, 2018 and December 31, 2023, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services. For general care management services furnished on or after January 1, 2024, the payment amount is based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data.

* * * * *

■ 13. Section 405.2468 is amended by revising paragraphs (b)(1), (b)(3), and (d)(2)(ii) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(b) * * *

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, certified nurse-midwife, visiting registered professional or licensed practical nurse, clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor who owns, is employed by, or furnishes services under contract to a FQHC or RHC.

* * * * *

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

* * * * *

(d) * * *

(2) * * *

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors.

* * * * *

■ 14. Section 405.2469 is amended by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, beginning January 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 15. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 16. Section 410.10 is amended by revising paragraph (l) and adding paragraphs (z) and (aa) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(l) Pneumococcal, influenza, and COVID–19 vaccines (or monoclonal antibodies used for preexposure prophylaxis of COVID–19) and their administration.

* * * * *

(z) Marriage and Family Therapist services, as provided in § 410.53.

(aa) Mental Health Counselor services, as provided in § 410.54.

■ 17. In § 410.15 amend paragraph (a) by:

■ a. In the definition of ''First annual wellness visit providing personalized prevention plan services'':

■ i. Redesignating paragraph (xiii) as paragraph (xiv); and

■ ii. Adding a new paragraph (xiii).

■ b. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'':

■ i. Redesignating paragraph (xi) as paragraph (xii); and

■ ii. Adding a new paragraph (xi).

The additions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

First annual wellness visit providing personalized prevention plan services * * *

(xiii) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services * * *

(xi) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

* * * * *

■ 18. Amend § § 410.18 by:

■ a. In paragraph (a):

■ i. In the definition of ''Diabetes'' removing the text ''diagnosed using the following criteria: a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''; and

■ ii. Removing the definition of ''Pre-diabetes''.

■ b. Redesignating paragraph (c)(3) as paragraph (c)(4) and adding a new paragraph (c)(3); and

■ c. Revising paragraph (d).

The revisions and addition read as follows:

§ 410.18 Diabetes screening tests.

(a) * * *

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism.

* * * * *

(c) * * *

(3) Hemoglobin A1C test.

(d) *Amount of testing covered.* Medicare covers two tests within the 12-month period following the date of the most recent diabetes screening test of that individual.

* * * * *

§ 410.32 [Amended]

■ 19. Section 410.32 is amended by revising paragraphs (a)(2) and (b)(3)(ii) to read as follow:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) * * *

(2) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, marriage and family therapists, mental health

counselors, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

* * * * *

(b) * * *

(3) * * *

(ii) *Direct supervision* in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

■ 20. Section § 410.33 is amended by revising paragraph (g)(2) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(g) * * *

(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location (including additions and deletions of locations), changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

* * * * *

■ 21. Amend § 410.47 by:

■ a. In paragraph (a):

■ i. Adding the definition of ''Nonphysician practitioner'' in alphabetical order;

■ ii. Revising the definitions of ''Pulmonary rehabilitation'' and ''Supervising physician'';

■ b. Revising paragraphs (b)(3)(ii)(A) and (d) introductory text; and

■ c. Removing paragraph (d)(3).

The addition and revisions read as follows:

§ 410.47 Pulmonary rehabilitation program: Conditions of coverage.

(a) * * *

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

* * * * *

Pulmonary rehabilitation means a physician or nonphysician practitioner supervised program for COPD and certain other chronic respiratory diseases designed to optimize physical and social performance and autonomy.

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under pulmonary rehabilitation programs.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A) A physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

* * * * *

(d) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

* * * * *

■ 22. Amend § 410.49 by:

■ a. In paragraph (a):

■ i. Revising the definitions of ''Cardiac rehabilitation'' and ''Intensive cardiac rehabilitation (ICR) program'';

■ ii. Adding the definition of ''Nonphysician practitioner'' in alphabetical order; and

■ iii. Revising the definition of ''Supervising physician'';

■ b. Revising paragraphs (b)(3)(ii) and (e) introductory text; and

■ c. Removing paragraph (e)(3).

The revisions and addition read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

(a) * * *

Cardiac rehabilitation (CR) means a physician or nonphysician practitioner supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

* * * * *

Intensive cardiac rehabilitation (ICR) program means a physician or nonphysician practitioner supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in paragraph (c) of this section.

* * * * *

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

* * * * *

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.

(b) * * *

(3) * * *

(ii) All settings must have a physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

* * * * *

(e) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

* * * * *

■ 23. Add § 410.53 to subpart B to read as follows:

§ 410.53 Marriage and family therapist services.

(a) *Definition: marriage and family therapist.* For purposes of this part, a marriage and family therapist is defined as an individual who—

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;

(2) After obtaining such degree, has performed at least 2 years or 3,000 hours

of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

(b) *Covered marriage and family therapist services.* Medicare Part B covers marriage and family therapist services.

(1) *Definition: marriage and family therapist services* means services furnished by a marriage and family therapist (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not marriage and family therapist services for purposes of billing Medicare Part B under the MFT and MHC statutory benefit category:

(i) Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A marriage and family therapist may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A marriage and family therapist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

■ 24. Add § 410.54 to subpart B to read as follows:

§ 410.54 Mental health counselor services.

(a) *Definition: mental health counselor.* For purposes of this part, a *mental health counselor* is defined as an individual who—

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are performed.

(b) *Covered mental health counselor services.* Medicare Part B covers mental health counselor services.

(1) *Definition: Mental health counselor services* means services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not mental health counselor services for purposes of billing Medicare Part B:

(i) Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A mental health counselor may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A mental health counselor or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

■ 25. Section 410.57 is amended by revising paragraph (c) to read as follows:

§ 410.57 Preventive vaccines.

* * * * *

(c) Medicare Part B pays for the COVID–19 vaccine (or monoclonal antibodies used for pre-exposure prophylaxis of COVID–19) and its administration.

* * * * *

■ 26. Section 410.59 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(a) * * *

(3) * * *

(ii) By, or under the direct supervision (or as specified otherwise) of, an occupational therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of occupational therapy services.* Except as otherwise provided in this paragraph, occupational therapy services are performed by, or under the direct supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by an occupational therapy assistant under the general supervision of the occupational therapist in private practice; services performed by an unenrolled occupational therapist must be under the direct supervision of the occupational therapist.

* * * * *

■ 27. Section 410.60 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

* * * * *

(a) * * *

(3) * * *

(ii) By, or under the direct supervision (or as specified otherwise) of, a physical therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of physical therapy services.* Except as otherwise provided in this paragraph, physical therapy services are performed by, or under the direct supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by a physical therapist assistant under the general supervision of the physical therapist in private practice; services performed by an unenrolled physical therapist must be under the direct supervision of the physical therapist.

* * * * *

§ 410.67 [Amended]

■ 28. In § 410.67 amend paragraph (vii) in the definition of ''Opioid use disorder treatment service'' in paragraph (b) by removing the reference ''through the end of CY 2023'' and adding in its place

the reference ''through the end of CY 2024''.

■ 29. Section 410.72 is amended by revising paragraph (d) to read as follows:

§ 410.72 Registered dietitians' and nutrition professionals' services.

* * * * *

(d) *Professional services.* Except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

* * * * *

■ 30. Section 410.78 is amended by—

■ a. Adding paragraphs (b)(2)(x) through (xii);

■ b. Revising paragraphs (b)(3)(xiv) introductory text, (b)(4)(iv)(D), and (e)(1); and

■ c. Adding paragraph (e)(3).

The additions and revisions read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(2) * * *

(x) Any distant site practitioner who can appropriately report diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

(xi) A marriage and family therapist as described in 410.53.

(xii) A mental health counselor as described in 410.54.

(3) * * *

(xiv) The home of a beneficiary for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder for services that are furnished during the period beginning on the first day after the end of the emergency period as defined in our regulation at § 400.200 and ending on December 31, 2024 except as otherwise provided in this paragraph. Payment will not be made for a telehealth service furnished under this paragraph unless the following conditions are met:

(4) * * *

(iv) * * *

(D) Services furnished on or after January 1, 2025 for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder. Payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

* * * * *

(e) * * *

(1) A clinical psychologist and a clinical social worker, a marriage and family therapist (MFT), and a mental health counselor (MHC) may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

* * * * *

(3) The distant site practitioner who reports the DSMT services may bill and receive payment when a professional furnishes injection training for an insulin-dependent patient using interactive telecommunications technology when such training is included as part of the DSMT plan of care referenced at § 410.141(b)(2).

* * * * *

■ 31. Amend § 410.79 by:

■ a. In paragraph (b):

■ i. Adding the definition of ''Combination delivery'' in alphabetical order;

■ ii. Removing the definition of ''Core maintenance session interval'';

■ iii. Adding the definitions of ''Distance learning'', ''Extended flexibilities'', ''Extended flexibilities period'', and ''Full-Plus CDC DPRP recognition'' in alphabetical order;

■ iv. Revising the definitions of ''Make-up session'', ''MDPP services period'', and ''MDPP session''

■ v. Adding the definition ''Online delivery'' in alphabetical order;

■ vi. Removing the definition of ''Ongoing maintenance sessions'';

■ vii. Adding the definition of ''Virtual session'' in alphabetical order.

■ b. By removing paragraphs (c)(1)(ii) and (iii);

■ c. By redesignating paragraph (c)(1)(iv) as paragraph (c)(1)(ii);

■ d. By revising paragraphs (c)(2)(i)(A) and (B);

■ e. By removing and reserving paragraph (c)(2)(ii);

■ f. By revising paragraph (c)(3)(i);

■ g. By removing and reserving paragraph (c)(3)(ii); removing paragraph (c)(3)(iii), removing and reserving paragraphs (d)(2)(iii)(B) and (d)(3)(ii);

■ h. Revising paragraphs (e)(3)(iv) introductory text, (e)(3)(iv)(D), (e)(3)(iv)(F)(*1*) and (*2*).

The additions and revisions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(b) * * *

Combination delivery. MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.

* * * * *

Distance learning refers to an MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.

Extended flexibilities refer to the flexibilities as described in paragraphs (e)(3)(iii) and (iv) of this section.

Extended flexibilities period refers to the 4-year period (January 1, 2024 to December 31, 2027) for the Extended flexibilities to apply.

* * * * *

Full-Plus CDC DPRP recognition refers to organizations that have met the Full CDC DPRP recognition, and at the time full recognition is achieved, has met the following retention criterion: Eligible participants in the evaluation cohort must have been retained at the following percentages: A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions; A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

* * * * *

Make-up session means a core session or a core maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core maintenance session.

MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the Set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph (c)(2)(i) and, subject to paragraph (c)(3) of this section.

MDPP session means a core session or a core maintenance session.

* * * * *

Online delivery refers to an MDPP session that is delivered online for all

participants and is furnished in a manner consistent with the DPRP Standards for online sessions. The program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Coach teaching the content. However, live Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.

* * * * *

Virtual session refers to an MDPP session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for distance learning sessions.

(c) * * *

(2) * * *

(i) * * *

(A) Up to 16 core sessions offered at least 1 week apart during months 1 through 6 of the MDPP services period; and

(B) Up to 6 core maintenance sessions offered at least 1 month apart during months 7 through 12 of the MDPP services period

(ii) [Reserved]

(3) * * *

(i) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section.

* * * * *

(e) * * *

(3) * * *

(iv) The virtual session limits described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually, through distance learning or a combination of in-person or distance learning, during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. If the beneficiary began the MDPP services period virtually, or changed from in-person to virtual services during the Extended flexibilities period, a PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may continue to receive the Set of MDPP services virtually even after the PHE or 1135 waiver event has concluded, until the end of the beneficiary's MDPP services period, so long as the provision of virtual services complies with all of the following requirements:

* * * * *

(D) Virtual sessions are furnished in a manner consistent with the DPRP standards for distance learning sessions.

* * * * *

(F) * * *

(*1*) Up to 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(*2*) Up to 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period.

* * * * *

§ 410.130 [Amended]

■ 32. Amend § 410.130 in the definition of ''Diabetes'' by removing the text ''diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''.

§ 410.140 [Amended]

■ 33. Amend § 410.140 in the definition of ''Diabetes'' by removing the text ''diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes''.

■ 34. Amend § 410.150 by adding paragraphs (b)(21) and (22) to read follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(21) To a marriage and family therapist on the individual's behalf for marriage and family therapist services.

(22) To a mental health counselor on the individual's behalf for mental health counseling services.

■ 35. Section 410.152 is amended by:

■ a. Revising paragraphs (b) introductory text, (h)(2) and (h)(3), (h)(4) introductory text, (h)(5); and

■ b. Adding paragraphs (m) and (n).

The revisions and additions read as follows:

§ 410.152 Amounts of payment.

* * * * *

(b) *Basic rules for payment.* Except as specified in paragraphs (c) through (h) and (m) and (n) of this section, Medicare Part B pays the following amounts:

* * * * *

(h) * * *

(2) For the administration of a COVID–19 vaccine:

(i) Effective January 1, 2022, for administration of a COVID–19 vaccine, $40 per dose.

(ii) For services furnished on or after January 1 of the year following the year in which the Secretary ends the March 27, 2020 Emergency Use Authorization declaration for drugs and biologicals (issued at 85 FR 18250) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), for administration of a COVID–19 vaccine, an amount equal to the amount that would be paid for the administration of a preventive vaccine described in paragraph (h)(1) of this section.

(3) Subject to conditions specified in this paragraph, in addition to the payment described in paragraph (h)(1) or (2) of this section, an additional payment for preventive vaccine administration in the patient's home:

(i) Effective January 1, 2022 for administration of a COVID–19 vaccine in the home, an additional payment of $35.50.

(ii) Effective January 1, 2024, for the administration of one or more of the preventive vaccines described in paragraphs (h)(1) and (2) of this section in the home, a payment equal to that of the payment in paragraph (h)(3)(i) of this section.

(iii) An additional payment for preventive vaccine administration in the home can be made if:

(A) The patient has difficulty leaving the home, or faces barriers to getting a vaccine in settings other than their home.

(B) The sole purpose of the visit is to administer one or more preventive vaccines.

(C) The home is not an institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, or §§ 409.42(a) of this subchapter.

(4) The payment amount for the administration of a preventive vaccine described in paragraphs (h)(1) and (2) of this section, and the additional payment for the administration of a preventive vaccine in the home as described in paragraph (h)(3) of this section, is adjusted to reflect geographic cost variations:

* * * * *

(5) For services furnished on or after January 1, 2023, the payment amount for administration of a preventive vaccine described in paragraphs (h)(1) and (2) of this section, and the additional payment for the administration of a preventive vaccine

in the home as described in paragraph (h)(3) of this section, is updated annually using the percentage change in the Medicare Economic Index (MEI), as described in section 1842(i)(3) of the Act and § 405.504(d) of this subchapter.

* * * * *

(m) *Amount of payment: Rebatable drugs.* In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), including a selected drug (as defined in section 1192(c) of the Act), furnished by providers on or after April 1, 2023, in a calendar quarter during which the payment amount for such drug as specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, exceeds the inflation-adjusted amount (as defined in section 1847A(i)(3)(C) of the Act) for such drug, Medicare Part B pays, subject to the deductible, the difference between the allowed payment amount determined under section 1847A of the Act and 20 percent of the inflation-adjusted amount, which is applied as a percent to the payment amount for such calendar quarter.

(n) *Amount of payment: Insulin furnished through an item of durable medical equipment.* For insulin furnished on or after July 1, 2023 through an item of durable medical equipment (as defined in § 414.202), Medicare Part B pays the difference between the applicable payment amount for such insulin and the coinsurance amount, with the coinsurance amount not to exceed $35 for a month's supply.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 36. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 37. Section 411.15 is amended by revising paragraph (i)(3)(i)(A) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(A) Dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: organ transplant, hematopoietic stem cell transplant, bone marrow transplant, cardiac valve replacement, valvuloplasty procedures, chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, and radiation, chemotherapy, and surgery when used in the treatment of head and neck cancer.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 38. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 39. Section 414.53 is added to read as follows:

§ 414.53 Fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services.

The fee schedule for clinical social worker, marriage and family therapist, and mental health counselor services is set at 75 percent of the amount determined for clinical psychologist services under the physician fee schedule.

■ 40. Amend § 414.84 by:

■ a. In paragraph (a):

■ i. Adding the definition of ''Attendance payment'' in alphabetical order;

■ ii. Revising the definition of ''Performance goal'';

■ b. Revising paragraph (b) introductory text;

■ c. Removing paragraphs (b)(1) through (5);

■ d. Redesignating paragraphs (b)(6) and (7) as paragraphs (b)(1) and (2), respectively;

■ e. Revising newly redesignated paragraphs (b)(1) paragraph heading and (b)(1)(i);

■ f. Adding paragraph (b)(1)(iii);

■ g. Revising newly redesignated paragraphs (b)(2) paragraph heading and (b)(2)(i);

■ h. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively;

■ i. Adding new paragraph (c); and

■ j. Revising newly redesignated paragraphs (d)(1) and (e).

The additions and revisions read as follows:

§ 414.84 Payment for MDPP Services.

(a) * * *

Attendance payment means a payment that is made to an MDPP supplier for furnishing services to an MDPP beneficiary when the MDPP beneficiary attends an MDPP core or core maintenance session. CMS will allow up to 22 sessions (alone or in combination with other codes, not to exceed 22 sessions in a 12- month timeframe).

* * * * *

Performance goal means a weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

* * * * *

(b) *Performance payment.* CMS makes one or more types of performance payments to an MDPP supplier as specified in this paragraph (b). Each type of performance payment is made only if the beneficiary achieves the applicable performance goal and only once per MDPP beneficiary. A performance payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a performance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The two types of performance payments are as follows:

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss.* * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024 the amount is $145.

* * * * *

(iii) If the beneficiary maintains the required minimum weight loss during a core maintenance session, as measured in-person or described in § 410.79(e)(3)(iii) the amount is $8.

(2) *Performance Goal 2: Achieves 9-percent weight loss.* * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024. $25.

* * * * *

(c) *Attendance payment: Attends a core session or core maintenance session.* CMS makes a payment to an MDPP supplier if an MDPP beneficiary attends a core session or core maintenance session. An attendance

payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make an attendance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session.

(1) The first core session attended, which initiates the MDPP services period, and that first core session was furnished by that supplier.

(2) For the Extended flexibilities period described in § 410.79(e)(2)(iii), the distance learning HCPCS G-code applies for any Set of MDPP services that are delivered by distance learning, as described in § 410.79(b).

(3) Medicare pays for up to 22 sessions in a 12-month period. The amount of this payment is determined as follows:

(i) For a core session or core maintenance session furnished January 1, 2024 through December 31, 2024. $25.

(ii) [Reserved]

(d) * * *

(1) For core session or core maintenance session, as applicable, furnished January 1, 2024 through December 31, 2024 the amount is $25.

* * * * *

(e) *Updating performance payments, attendance payments, and the bridge payment.* The performance payments, attendance payments, and bridge payment will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

§ 414.94 [Removed]

■ 41. Remove § 414.94.

■ 42. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2024 through March 31, 2024, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2024 through March 31, 2024.

* * * * *

§ 414.504 [Amended]

■ 43. Amend § 414.504 in paragraph (a)(1) by removing the reference ''January 1, 2023'' and adding in its place the reference ''January 1, 2024''.

■ 44. Section 414.507 is amended by—

■ a. Revising paragraph (d) introductory text and paragraph (d)(6); and

■ b. Adding paragraph (d)(9).

The revisions and addition read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2026, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(6) 2023—0.0 percent of the payment rate established in 2022.

* * * * *

(9) 2026—15 percent of the payment rate established in 2025.

* * * * *

§ 414.610 [Amended]

■ 45. Amend § 414.610 in paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) by removing the date ''December 31, 2022'' and adding in its place the date ''December 31, 2024''

■ 46. Section 414.902 is amended by adding the definitions of ''Applicable five-year period'', ''Low volume dose'', ''New refund quarter'', ''Qualifying biosimilar biological product'', and ''Updated refund quarter'' in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Applicable five-year period means:

(1) For a qualifying biosimilar biological product for which payment has been made under section 1847A(b)(8) of the Act as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

(2) For a qualifying biosimilar biological product for which payment is first made under section 1847A(b)(8) of the Act during a calendar quarter during the period beginning October 1, 2022 and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

* * * * *

Low volume dose means, with respect to determination of whether an increased applicable percentage is warranted, an FDA-labeled dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL.

* * * * *

New refund quarter means a calendar quarter that is included in a report described in § 414.940(a) that is sent in the first year following the year in which the calendar quarter occurs.

* * * * *

Qualifying biosimilar biological product means a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an average sales price (as described in section 1847A(b)(8)(A)(i) of the Act) less than the average sales price of the reference biological for a calendar quarter during the applicable 5-year period.

* * * * *

Updated refund quarter means a calendar quarter that is included in a report described in § 414.940(a) that is sent in the second year following the year in which the calendar quarter occurs.

* * * * *

■ 47. Section 414.904 is amended by revising paragraphs (e)(4) and (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(4) *Payment amount in a case where the average sales price during the first quarter of sales is unavailable.* During an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price:

(i) *In general.* Except as provided in paragraph (e)(4)(ii) of this section,

(A) For dates of service before January 1, 2019, the payment amount for the drug is based on the wholesale acquisition cost or the Medicare Part B drug payment methodology in effect on November 1, 2003.

(B) For dates of service on or after January 1, 2019, the payment amount for the drug is an amount not to exceed 103 percent of the wholesale acquisition cost or based on the Medicare Part B drug payment methodologies in effect on November 1, 2003.

(ii) *Limitation on payment amount for biosimilar biological products during initial period.* For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902) during the initial period is the lesser of the following:

(A) The payment amount for the biosimilar biological product as determined under clause (e)(4)(i)(B) of this section or

(B) 106 percent of the amount determined under section 1847A(b)(1)(B) of the Act for the reference biological product (as defined in § 414.902).

* * * * *

(j) *Biosimilar biological products*—(1) *In general.* Except as provided in paragraph (j)(2), effective January 1, 2016, the payment amount for a biosimilar biological product (as defined in § 414.902), for all NDCs assigned to such product, is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act, and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902).

(2) *Temporary increase in Medicare Part B payment for qualifying biosimilar biological products.* In the case of a qualifying biosimilar biological product (as defined in § 414.902) that is furnished during the applicable five-year period (as defined in § 414.902) for such product, the payment amount for such product with respect to such period is the sum determined under as determined under section 1847A(b)(6) of the Act and 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902).

■ 48. Section 414.940 is amended by—

■ a. Redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(iv).

■ b. Adding new paragraph (a)(1)(iii).

■ c. Revising paragraphs (a)(3), (b)(1) and (2), (c), and (d);

■ d. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively; and

■ e. Adding new paragraph (e).

The revisions and additions read as follows:

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) * * *

(1) * * *

(iii) Reports will include information in paragraphs (a)(1)(i) and (ii) of this section for new refund quarters and updated refund quarters (as defined at § 414.902).

* * * * *

(3) *Report Timing.* Reports are sent once annually.

(b) * * *

(1) Refund amounts for which the manufacturer is liable, pursuant to this paragraph, must be paid by December 31 of the year in which the report described in paragraph (a) of this section is sent, except that refund amounts for which the manufacturer is liable, pursuant to this paragraph, for amounts in the initial report for calendar quarters in 2023 must be paid no later than February 28, 2025.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than the dates specified in paragraph (b)(1) of this section or 30 days following the resolution of the dispute, whichever is later.

* * * * *

(c) *Refund amount.* The amount of the refund specified in this paragraph is with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code (except as provided in paragraph (c)(4) of this section) for:

(1) A new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;

(ii) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

(2) The refund amount owed by a manufacturer for an updated refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such updated refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(ii) Exceeds the difference of:

(A) An amount equal to the applicable percentage of the estimated total allowed charges for such a drug during the updated refund quarter; and

(B) The refund amount already paid for such refundable drug for such quarter.

(3) Negative refund amount for an updated refund quarter. If the refund amount described in paragraph (c)(2) of this section is negative, the amount will be netted from refunds owed for other updated and new refund quarters included in the same report as such updated refund quarter.

(4) Exception when there are multiple manufacturers. If there is more than one manufacturer of a refundable single-dose container or single-use package drug for a quarter, the refund amount for which a manufacturer is liable is an amount equal to the estimated amount (if any) by which—

(i) The product of the amount calculated in paragraph (c)(1) of this section and the percentage of billing unit sales (of the applicable billing and payment code attributed to the National Drug Code; exceeds:

(ii) The product of the amount in paragraph (c)(2) of this section and percentage of billing unit sales of the applicable billing and payment code attributed to the National Drug Code.

(iii) The number of billing unit sales for each NDC is the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC.

(d) *Applicable percentage.* For purposes of paragraph (c) of this section, and except as provided in paragraph (e) of this section, the applicable percentage is:

(1) 10 percent, unless specified otherwise in this section.

(2) 35 percent for a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics.

(3) 90 percent for a drug with a low volume dose (as defined at § 414.902 of this part) contained within 0.1 mL or less.

(4) 45 percent for a drug with a low volume dose (as defined in § 414.902 of

this part) contained within 0.11 mL up to 0.4 mL.

(5) 26 percent for a drug designated an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition (or diseases or conditions) and approved by the FDA only for one or more indications within such designated rare disease or condition (or diseases or conditions) and is furnished to fewer than 100 unique beneficiaries per calendar year.

(e) *Application process for increased applicable percentage.* Manufacturers may submit an application to CMS requesting consideration of an increased applicable percentage for purposes of paragraph (c) of this section because of the drug's unique circumstances. The process for submitting such an application is as follows:

(1) *Application.* An application must include:

(i) A written request that a drug be considered for an increased applicable percentage based on its unique circumstances;

(ii) FDA-approved labeling;

(iii) Justification for the consideration of an increased applicable percentage based on such unique circumstances; and

(iv) Justification for the requested applicable percentage.

(2) *Application timeline.* An application must be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply.

(3) *Application processing.* Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage for purposes of paragraph (c) beginning as of the following January 1.

* * * * *

■ 49. Section 414.1305 is amended by—

■ a. In the definition of ''Attestation'', by removing the term ''MIPS eligible clinician or group'' and adding in its in place the term ''MIPS eligible clinician, subgroup, or group''.

■ b. In the definition of ''Attribution-eligible beneficiary'', by revising paragraph (6);

■ c. In the definition of ''Certified Electronic Health Record Technology (CEHRT)'', by revising paragraphs (2) introductory text and (2)(ii), and adding paragraph (3);

■ d. By revising the definition of ''Collection type'';

■ e. By adding the definition of ''Qualified posting''.

■ f. In the definition of ''Submitter type'', by removing the term ''MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary'' and adding in its place the term the ''MIPS eligible clinician, group, Virtual Group, subgroup, APM Entity, or third party intermediary.''

The revisions and addition read as follows:

§ 414.1305 Definitions.

* * * * *

Attribution-eligible beneficiary * * *

* * * * *

(6) Has a minimum of one claim for covered professional services furnished by an eligible clinician who is on the Participation List for an Advanced APM Entity at any determination date during the QP Performance Period.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

* * * * *

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102), and has been certified to the ONC health IT certification criteria as adopted and updated in 45 CFR 170.315—

* * * * *

(ii) Necessary to report on applicable objectives and measures specified for MIPS including the following:

* * * * *

(3) For purposes of determinations under §§ 414.1415 and 414.1420, beginning for CY 2024, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets—

(i) The 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined in 45 CFR 170.102); and

(ii) Any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice area, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; and Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs).

* * * * *

Qualified Posting means the document made available that lists qualified registries or QCDRs available by CMS for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities.

* * * * *

■ 50. Section 414.1320 is amended by—

■ a. Revising paragraph (h) introductory text; and

■ b. Adding paragraph (i).

The addition and revision read as follow:

§ 414.1320 MIPS performance period.

* * * * *

(h) For purposes of the 2024 MIPS payment year and the 2025 MIPS payment year, the performance period for:

* * * * *

(i) For purposes of the 2026 MIPS payment year and each subsequent payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 51. Section 414.1325 is amended by revising paragraphs (a)(1), (c) introductory text, and (d) to read as follows.

§ 414.1325 Data submission requirements.

(a) * * *

(1) Except as provided in paragraph (a)(2) of this section, or under § 414.1370 or § 414.1365(c), as applicable, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance

with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by a third party intermediary described at § 414.1400.

* * * * *

(c) *Data submission types for groups, virtual groups, subgroups, and APM Entities.* Groups, virtual groups, subgroups, and APM Entities may submit their MIPS data using:

* * * * *

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year as applicable to MIPS eligible clinicians, groups, and virtual groups, beginning with the 2023 MIPS payment year as applicable to APM Entities, and beginning with the 2025 MIPS payment year as applicable to subgroups, MIPS eligible clinicians, groups, virtual groups, APM Entities, and subgroups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, virtual group, APM Entity, or subgroup uses the same identifier for all performance categories and all data submissions.

■ 52. Section 414.1335 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(1)(i), (a)(1)(ii), (a)(3) paragraph heading, and (a)(3)(i); and

■ b. Adding paragraph (a)(4).

The revisions and additions read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* A MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must submit data on MIPS quality measures in one of the following manners, as applicable:

(1) * * *

(i) Except as provided in paragraph (a)(1)(ii) of this section, submits data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, reports one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician, group, virtual group, or APM Entity, reports on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(B) [Reserved]

(ii) A MIPS eligible clinician, group, virtual group, and APM Entity that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, group, virtual group, or APM Entity, report on each measure that is applicable.

(A) For eCQMs, the submission of data requires the utilization of CEHRT, as defined at § 414.1305.

(B) [Reserved]

* * * * *

(3) *For the CAHPS for MIPS survey measure.* (i) For the 12-month performance period, a group, virtual group, subgroup, or APM Entity that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

* * * * *

(4) *For Medicare CQMs.* (i) A MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

* * * * *

■ 53. Section 414.1340 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Adding paragraphs (a)(2)(i) and (a)(3)(i) and (ii);

■ c. Revising paragraph (a)(4);

■ d. Adding paragraph (a)(5);

■ e. Revising paragraph (b) introductory text;

■ f. Adding paragraphs (b)(2)(i) and (ii) and (b)(3)(i) and (ii);

■ g. Revising paragraph (b)(4);

■ h. Adding paragraph (b)(5);

■ i. Revising paragraph (d); and

■ j. Adding paragraph (e).

The revisions and additions read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on:

* * * * *

(2) At least 60 percent of the MIPS eligible clinician, group, and virtual group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2020 and 2021.

(3) At least 70 percent of the MIPS eligible clinician, group, and virtual group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2022, 2023, 2024, and 2025.

(i) Applicable to an APM Entity for MIPS payment years 2023, 2024, and 2025.

(ii) Applicable to a subgroup for MIPS payment year 2025.

(4) At least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026, 2027, and 2028.

(5) At least 80 percent of the MIPS eligible clinician, group, virtual group, subgroup, or and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2029.

(b) MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measure data on Medicare Part B claims measures must submit data on:

* * * * *

(2) * * *

(i) Applicable to virtual groups starting with MIPS payment year 2020.

(ii) [Reserved]

(3) * * *

(i) Applicable to APM Entities starting with MIPS payment year 2023 and subgroups starting with MIPS payment year 2025.

(ii) [Reserved].

* * * * *

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026, 2027, and 2028.

(5) At least 80 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2029.

* * * * *

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment years 2026, 2027, and 2028.

(2) At least 80 percent of the applicable beneficiaries eligible for the

Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2029.

(e) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 54. Section 414.1350 is amended by revising paragraphs (c)(4) through (6) and adding paragraph (c)(7) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(c) * * *

(4) For the procedural episode-based measures specified beginning with and after the CY 2019 performance period/2021 MIPS payment year, the case minimum is 10, unless otherwise specified for individual measures. Beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum for Colon and Rectal Resection procedural episode-based measure is 20 episodes.

(5) For the acute inpatient medical condition episode-based measures specified beginning with and after CY 2019 performance period/2021 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(6) For the chronic condition episode-based measures specified beginning with and after the CY 2022 performance period/2024 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

(7) For the care setting episode-based measures specified beginning with and after the CY 2024 performance period/2026 MIPS payment year, the case minimum is 20, unless otherwise specified for individual measures.

* * * * *

■ 55. Section 414.1360 is amended by revising paragraph (a) introductory text to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) For purposes of the transition year of MIPS and future years, MIPS eligible clinicians, subgroups, or groups must submit data on MIPS improvement activities in one of the following manners:

* * * * *

■ 56. Section 414.1365 is amended by—

■ a. Revising paragraphs (e)(2)(ii) introductory text and (e)(3); and

■ b. Adding paragraphs (e)(4)(i) and (ii).

The revisions and addition read as follow:

§ 414.1365 MIPS Value Pathways.

* * * * *

(e) * * *

(2) * * *

(ii) *Subgroups.* For an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, for the CY 2023 performance period/2025 MIPS payment year, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the following circumstances independent of the affiliated group:

* * * * *

(3) *Facility-based scoring.* If an MVP Participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score also will be calculated in accordance with § 414.1380(e).

(4) * * *

(i) For subgroups, the affiliated group's complex patient bonus will be added to the final score.

(ii) [Reserved]

■ 57. Section 414.1375 is amended by revising paragraph (b)(2)(ii)(C), and adding paragraph (b)(2)(ii)(D) to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(A) * * *

(B) * * *

(C) Beginning with the 2024 MIPS payment year through the 2025 MIPS payment year, submit an attestation, with either an affirmative or negative response, with respect to whether the MIPS eligible clinician completed the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

(D) Beginning with the 2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the SAFER Guides measure during the year in which the performance period occurs.

* * * * *

■ 58. Section 414.1380 is amended by—

■ a. Revising paragraphs (a)(1)(i) and (ii), (b)(1)(v)(A), (b)(2)(iv)(A), (B), (C) and (E), (b)(3)(i), and (c)(2)(i)(A)(*4*)(*iii*);

■ b. Adding paragraphs (c)(2)(iv);

■ c. In paragraph (c)(3)(v) removing the term ''MIPS eligible clinicians, groups, subgroups, APM Entities and virtual groups'' and adding in its place the term ''MIPS eligible clinicians, groups, APM Entities and virtual groups;'' and

■ d. In paragraph (c)(3)(vi) removing the term ''MIPS eligible clinicians, groups, and subgroups'' and adding in its place the term ''MIPS eligible clinicians and groups''.

The revisions and additions read as follow:

§ 414.1380 Scoring.

(a) * * *

(1) * * *

(i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Prior to the CY 2023 performance period/2025 MIPS payment year, measure bonus points are available for submitting high-priority measures and submitting measures using end-to-end electronic reporting. Measure bonus points are available for small practices that submit data on at least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Beginning with the 2025 MIPS payment year, improvement scoring is available in the cost performance category.

* * * * *

(b) * * *

(1) * * *

(v) * * *

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning in the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points.

* * * * *

(2) * * *

(iv) * * *

(A) The cost improvement score is determined at the category level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement are available. Sufficient data are available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the cost performance category for 2 consecutive

performance periods. If the cost improvement score cannot be calculated because sufficient data are not available, then the cost improvement score is zero.

(C) The cost improvement score is determined at the category-level by subtracting the cost performance category score from the previous performance period from the cost performance category percent score from the current performance period, and then by dividing the difference by the cost performance category score from the previous performance period, and by dividing by 100.

* * * * *

(E) The maximum cost improvement score for the 2020, 2021, 2022, 2023, and 2024 MIPS payment year is zero percentage points. The maximum cost improvement score beginning with the 2025 MIPS payment year is 1 percentage point.

* * * * *

(3) * * *

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent. MIPS eligible clinicians participating in APMs must attest to having completed an improvement activity or submit data for the quality and Promoting Interoperability performance categories in order to receive such credit.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) * * *

(*iii*) For the 2024 through 2026 MIPS payment years, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be distributed.

* * * * *

(iv) If CMS has granted an application for a hardship exception or any other type of exception to a MIPS eligible clinician under paragraph (c)(2)(i)(A)(*6*) or (c)(2)(i)(C)(*2*) of this section, or has identified a MIPS eligible clinician in a CMS-designated region as being affected by an automatic extreme and uncontrollable circumstances event under paragraph (c)(2)(i)(A)(*8*) or (c)(2)(i)(C)(*3*) of this section, CMS will not apply the improvement activities score described in paragraph (b)(3)(i) of this section to the MIPS eligible clinician's score.

* * * * *

■ 59. Section 414.1385 is amended—

■ a. In paragraph (a) by removing the term ''MIPS eligible clinician or group'' and adding in its in place the term ''MIPS eligible clinician, virtual group, subgroup or group;''

■ b. In paragraph (a)(1) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, or group;''

■ c. By revising paragraph (a)(2);

■ d. In paragraph (a)(3) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, group;''

■ e. By revising paragraph (a)(5); and

■ f. In paragraph (a)(6) by removing the term ''MIPS eligible clinician or group'' and adding in its place the term ''MIPS eligible clinician, virtual group, subgroup, or group''.

The revisions read as follows:

§ 414.1385 Targeted review and review limitations.

(a) * * *

(2) All requests for targeted review must be submitted during the targeted review request submission period, which begins on the day CMS makes available the MIPS final score, and ends 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

* * * * *

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician, subgroup, virtual group, or group that is the subject of a request for a targeted review, the information must be provided and received by CMS within 15 days of CMS' request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another non-duplicative request for targeted review may be submitted before the end of the targeted review request submission period.

* * * * *

■ 60. Section 414.1400 is amended by—

■ a. Revising paragraphs (a)(1)(iii), (a)(2)(i), (a)(2)(ii)(A), (a)(3), and (b)(1)(ii);

■ b. Adding paragraphs (b)(1)(iii);

■ c Revising paragraphs (b)(2), (b)(3)(v)(E)(*1*) and (*2*);

■ d. Adding paragraphs (b)(3)(ix) through (xvii);

■ e. Revising paragraph (b)(4)(i)(B);

■ f. Adding paragraphs (b)(4)(i)(C) and (b)(4)(iv)(O) and (P);

■ g. Revising paragraph (e)(1) introductory text;

■ h. Adding paragraph (e)(1)(i)(F);

■ i. Revising paragraph (e)(1)(ii);

■ j. Adding paragraphs (e)(2)(iv) and (v);

■ k. Revising paragraphs (e)(3) and (4) and (f).

The additions and revisions read as follows:

§ 414.1400 Third party intermediaries.

(a)* * *

(1)* * *

(iii) Before the CY 2025 performance period/2027 payment year, Health IT vendor;

* * * * *

(2) * * *

(i) To be approved as a third party intermediary, an organization must meet the following requirements:

(A) The organization's principal place of business and the location in which it stores data must be in the U.S.

(B) The organization must have the ability to indicate the source of any data it will submit to CMS if the data will be derived from CEHRT, a QCDR, qualified registry, or health IT vendor.

(C) The organization must certify that it intends to provide services throughout the entire performance period and applicable data submission period.

(ii) * * *

(A) Whether the organization failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary, including past compliance; and

* * * * *

(3) For third-party intermediary program requirements:

(i) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(ii) All data submitted to CMS by a third party intermediary must be submitted in the form and manner specified by CMS.

(A) The submission of data on measures by a third party intermediary to CMS must include data on all of the MIPS eligible clinician's patients, regardless of payer, unless otherwise specified by the collection type.

(B) [Reserved]

(iii) If the clinician chooses to opt-in to participate in MIPS in accordance with § 414.130, the third party intermediary must be able to transmit that decision to CMS.

(iv) Prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, a third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan by a date specified by CMS. The transition plan must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the withdrawal mid-performance period or discontinuation of services mid-performance period.

(B) Impacted entities:

(*1*) The number of clinicians, groups, virtual groups, subgroups or APM entities (inclusive of MIPS eligible, opt-in and voluntary participants) that would need to find another way to report.

(*2*) As applicable, identify any QCDRs that were granted licenses to QCDR measures which would no longer be available for reporting due to the transition.

(C) The steps the third party intermediary will take to ensure that the clinicians, groups, virtual groups, subgroups, or APM Entities identified in paragraph (a)(3)(iv)(B)(1) of this section are notified of the transition in a timely manner, and successfully transitioned to an alternate third party intermediary, submitter type, or, for any measure or activity on which data has been collected, collection type, as applicable.

(D) A detailed timeline that outlines timing for communications, the start of the transition, and completion of the transition of these clinicians, groups, virtual groups, subgroups, or APM Entities.

(E) The third party intermediary must communicate to CMS that the transition was completed by the date included in the detailed timeline.

(v) As a condition of its qualification and approval to participate in MIPS as a third party intermediary, a third party intermediary must:

(A) Make available to CMS the contact information of each MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity phone number, address, and, if available, email.

(B) Retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(C) Upon request, provide CMS with any records or data retained in connection with its operation as a third party intermediary for up to 6 years from the end of the MIPS performance period.

(vi) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

(b) * * *

(1) * * *

(ii) Beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. A QCDR or qualified registry must support all measures and activities included in the MVP with the following exceptions:

(A) If an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry are required to report those measures pertinent to the specialty of its MIPS eligible clinicians.

(B) If an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

(iii) Beginning with the CY 2023 performance period/2025 MIPS payment year, A QCDR or qualified registry must support subgroup reporting.

(2) *Self-nomination.* For the CY 2019 performance period/2021 MIPS payment year and future years, an existing QCDR or qualified registry that is in good standing may use the Simplified Self-Nomination process form during the self-nomination period, from July 1 and September 1 of the CY preceding the applicable performance period.

(3) * * *

(v) * * *

(E) * * *

(*1*) Uses a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.

(*2*) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

* * * * *

(ix) During the self-nomination period, a QCDR or a qualified registry must submit to CMS quality measure numbers, Promoting Interoperability identifiers, improvement activity identifiers and MVP titles.

(x) A QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure.

(A) If no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure.

(B) [Reserved]

(xi) A QCDR or a qualified registry must submit to CMS risk-adjusted measure results when submitting data for measures that include risk adjustment in the measure specification.

(xii) A QCDRs or qualified registry must enter into appropriate Business Associate Agreements with MIPS eligible clinicians to collect and process their data.

(xiii) A QCDR or a qualified registry must maintain records of their authorization to submit data to CMS for the purpose of MIPS participation for each NPI whom the QCDR or qualified registry will submit data to CMS for. The records must:

(A) Be annually obtained by the QCDR or qualified registry at the time the clinician or group enters into an agreement with the QCDR or qualified registry for the submission of MIPS data to the QCDR or qualified registry.

(B) Be signed by an eligible clinician, if reporting individually, or by an authorized representative of the reporting group, subgroup, Virtual Group, or APM Entity.

(C) Records of the authorization must be maintained for 6 years after the performance period ends.

(xiv) A QCDR or a qualified registry must attest that the information listed on the qualified posting is accurate.

(xv) A QCDR or a qualified registry must provide to CMS, upon request, the data submitted by the QCDR or qualified registry *for purposes of MIPS.*

(xvi) A QCDR or qualified registry must attest to the following:

(A) A QCDR or a qualified registry must attest that it has required each MIPS eligible clinician on whose behalf it reports to provide the QCDR or qualified registry with all documentation necessary to verify the accuracy of the data on quality measures that the eligible clinician submitted to the QCDR or qualified registry.

(B) A QCDR or qualified registry must also attest that it has required each MIPS eligible clinician to permit the QCDR or qualified registry to provide the information described in paragraph (b)(3)(xviii)(A) of this section to CMS upon request.

(xvii) A QCDR or a qualified registry must accept and maintain clinician data by January 1 of the applicable performance period.

(4) * * *

(i) * * *

(B) For a QCDR measure, the entity must submit for CMS approval measure specifications including: Name/title of measure, descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted. The approved QCDR measure specifications must remain published through the performance period and data submission period.

(C) For a QCDR measure, the QCDR must provide, if available, data from years prior before the start of the performance period.

* * * * *

(iv) * * *

(O) QCDR measures submitted after self-nomination.

(P) More than 30 QCDR measures are submitted by a single QCDR.

* * * * *

(e) * * *

(1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, failed to comply with the program requirements of this section, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) * * *

(F) Once the issue has been resolved, the detailed final resolution and an update, if any, to the monitoring plan provided pursuant to § 414.1400(e)(1)(i)(C).

(ii) Publicly disclose as follows:

(A) For the purposes of the CY 2025 performance period/2027 MIPS payment year and prior reporting periods and payment years, publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(B) Beginning with the CY 2025 performance period/2027 MIPS payment year, publicly disclose on the CMS website that CMS took remedial action against or terminated the third party intermediary.

(2) * * *

(iv) The third party intermediary has not maintained current contact information for correspondence.

(v) The third party intermediary is on remedial action for two consecutive years.

(3) A data submission that contains data inaccuracies affecting the third party intermediary's clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

(4) For purposes of this paragraph (e), CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, if the submitted data includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies.

* * * * *

(f) *Auditing of entities submitting MIPS data.* Third party intermediaries may be randomly selected for compliance evaluation or may be selected at the suggestion of CMS if there is an area of concern regarding the third party intermediary. For example, areas of concern could include, but are not limited to: high data errors, support call absences, delinquent deliverables, remedial action status, clinician concerns regarding the third party intermediary, a continuing pattern of Quality Payment Program Service Center inquiries or support call questions, and/or CMS concerns regarding the third party intermediary.

■ 61. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(9)(iii); and

■ b. Revising paragraph (g).

The addition and revision read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(9) * * *

(iii) The performance threshold for 2026 MIPS payment year is 82 points. The prior period to determine the performance threshold is the 2019 through 2021 MIPS payment years.

* * * * *

(g) *Performance threshold methodology.* (1) For each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section.

(2) For purposes of establishing a performance threshold as identified in § 414.1405(b), beginning with the 2026 MIPS payment year, a prior period is a time span of three performance periods.

■ 62. Section 414.1415 is amended by revising paragraph (a) to read as follows:

§ 414.1415 Advanced APM criteria.

(a) *Use of certified electronic health record technology (CEHRT)*—(1) *Required use of CEHRT.* To be an Advanced APM, an APM must:

(i) For QP Performance Periods ending with 2018, require at least 50 percent, or for QP Performance Periods beginning with 2019 and ending with 2023, 75 percent, of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers;

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity; and

(iii) For QP Performance Periods beginning with 2024, require use of CEHRT as defined at paragraph (3) under CEHRT at § 414.1305.

(2) [Reserved].

* * * * *

■ 63. Section 414.1420 is amended by revising paragraph (b) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(b) *Use of CEHRT.* To be an Other Payer Advanced APM:

(1) CEHRT must be used, for QP Performance Periods ending with 2019, by at least 50 percent; and for QP Performance Periods for 2020 through 2023, by at least 75 percent, of participants in each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care; and

(2) For QP Performance Periods beginning on or after January 1, 2024, use of CEHRT (as defined in § 414.1305, paragraph (3) in the definition of ''Certified Electronic Health Record Technology (CEHRT)''), must be a requirement of participation in the APM.

* * * * *

■ 64. Section 414.1425 is amended by adding paragraph (b)(3) to read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(b) * * *

(3) *Individual QP determinations.* For QP Performance Periods beginning for calendar year 2024, except as provided in paragraph (b)(2) of this section and in § 414.1440, QP determinations are made individually at the eligible clinician level. To be assessed as a QP, an eligible clinician's APM participant identifier must be included on the Participation List of an APM Entity participating in an Advanced APM on one of the following dates during the QP Performance Period: March 31, June 30, or August 31. An eligible clinician included on such a Participation List on any one of these dates is assessed as a QP even if the eligible clinician is not included on the Participation List at one of the prior or later listed dates. CMS performs QP determinations for the identified eligible clinicians during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates for which the eligible clinician is included on the Participation List: March 31, June 30, and August 31.

* * * * *

■ 65. Section 414.1430 is amended by—
■ a. Revising paragraph (a)(1)(iv);
■ b. Adding paragraph (a)(1)(v);
■ c. Revising paragraph (a)(2)(iv);
■ d. Adding paragraph (a)(2)(v);
■ e. Revising paragraph (a)(3)(iv);
■ f. Adding paragraph (a)(3)(v);
■ g. Revising paragraph (a)(4)(iv);
■ h. Adding paragraph (a)(4)(v); and
■ i. Revising paragraph (b)(1)(i)(A) and (B), (b)(2)(i)(A) and (B), (b)(3)(i)(A) and (B), (b)(4)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *
(1) * * *
(iv) 2025: 50 percent.
(v) 2026 and later: 75 percent.
(2) * * *
(iv) 2025: 40 percent.
(v) 2026 and later: 50 percent.
(3) * * *
(iv) 2025: 35 percent.
(v) 2026 and later: 50 percent.
(4) * * *
(iv) 2025: 25 percent.
(v) 2026 and later: 35 percent.
(b) * * *
(1) * * *
(i) * * *
(A) 2021 through 2025: 50 percent.
(B) 2026 and later: 75 percent.

* * * * *

(2) * * *
(i) * * *
(A) 2021 through 2025:40 percent.
(B) 2026 and later: 50 percent.

* * * * *

(3) * * *
(i) * * *
(A) 2021 through 2025: 35 percent.
(B) 2026 and later: 50 percent.

* * * * *

(4) * * *
(i) * * *
(A) 2021 through 2025: 25 percent.
(B) 2026 and later: 35 percent.

* * * * *

■ 66. Section 414.1450 is amended by—
■ a. Adding paragraphs (a)(1)(i) and (ii); and
■ b. Revising paragraph (b)(1).

The addition and revision read as follows:

§ 414.1450 APM incentive payment.

(a) * * *

(i) For payment years 2019 through 2025, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section.

(ii) [Reserved]

* * * * *

(b) * * *

(1) For payment years 2019 through 2024, the amount of the APM Incentive Payment is equal to 5 percent or, with respect to payment year 2025, 3.5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 67. The authority for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 415.140 [Amended]

■ 68. In § 415.140 in paragraph (a) amend the definition of ''Substantive portion'' by removing the reference ''year 2022 and 2023'' and adding in its place the reference ''years 2022 through 2024''.

PART 418—HOSPICE CARE

■ 69. The authority citation for part 418 continues to read as follow:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 70. Section 418.56 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

* * * * *

(a) * * *
(1) * * *

(iii) A social worker, marriage and family therapist, or a mental health counselor, depending on the preferences and needs of the patient.

* * * * *

■ 71. Section 418.114 is amended by adding paragraphs (c)(3) and (4) to read as follows:

§ 418.114 Condition of participation: Personnel qualifications.

* * * * *

(c) * * *

(3) Marriage and family counselor as defined at § 410.53.

(4) Mental health counselor as defined at § 410.54.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 72. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–22 through 1395w–28, and 1395hh.

■ 73. Section 422.310 is amended by adding paragraph (f)(3)(iv) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) * * *
(3) * * *

(iv) CMS determines that releasing aggregated data before reconciliation is

necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 74. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 75. Section 423.160 is amended by—

■ a. Revising paragraph (a)(5) introductory text;

■ b. Removing paragraph (a)(5)(i);

■ c. Redesignating paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively and revising newly redesignated paragraph (a)(5)(ii).

The revisions read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

* * * * *

(ii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify which emergencies or disasters qualify for this exception.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 76. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 77. Section 424.205 is amended by—

■ a. In paragraph (a), by removing the definition of ''MDPP interim preliminary recognition'';

■ b. Revising paragraph (b)(1);

■ c. Removing paragraph (c);

■ d. Redesignating paragraphs (d) through (i) as paragraphs (c) through (h), respectively; and

■ e. Revising newly designated paragraph (c)(1);

■ f. Removing newly redesignated paragraph (c)(10)(iii);

■ g. Revising newly redesignated paragraph (c)(14);

■ h. Revising newly redesignated paragraphs (f)(2)(i);

■ i. Removing newly redesignated paragraph (f)(5)(iii);

■ j. Redesignating newly redesignated paragraphs (f)(5)(iv) and (v) as paragraphs (f)(5)(iii) and (iv), respectively;

■ k. Revising newly redesignated paragraph (f)(5)(iii) and paragraph (g)(1)(i)(C).

The revisions read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(b) * * *

(1) Has either preliminary, full, full plus CDC DPRP recognition.

* * * * *

(c) * * *

(1) The MDPP supplier must have and maintain preliminary, full, or full plus CDC DPRP recognition.

* * * * *

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who ever attended ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core services period.

* * * * *

(f) * * *

(2) * * *

(i) Documentation of the type of session, whether a core session, a core maintenance session, an in-person make-up session, or a virtual make-up session.

* * * * *

(5) * * *

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(7) of this chapter.

* * * * *

(g) * * *

(1) * * *

(i) * * *

(C) An MDPP supplier that does not satisfy the requirements in paragraph (b)(1) of this section may become eligible to bill for MDPP services again if it successfully achieves preliminary, full, or full plus CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

* * * * *

■ 78. Section 424.210 is amended by revising paragraphs (b)(2) and (d)(1) to read as follows:

§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

* * * * *

(b) * * *

(2) The item or service must be reasonably connected to the CDC-approved National Diabetes Prevention Program curriculum furnished to the MDPP beneficiary during a core session or core maintenance session furnished by the MDPP supplier.

* * * * *

(d) * * *

(1) Attendance at core sessions or core maintenance sessions.

* * * * *

■ 79. Section 424.502 is amended by—

■ a. Revising the definition of ''Authorized official''; and

■ b. Adding the definitions of ''Indirect ownership interest,'' ''Pattern or practice,'' and ''Supplier'' in alphabetical order.

The revision and additions read as follows:

§ 424.502 Definitions.

* * * * *

Authorized official means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program. For purposes of this definition only, the term ''organization'' means the enrolling entity as identified by its legal business name and tax identification number.

* * * * *

Indirect ownership interest means as follows:

(1)(i) Any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier.

(ii) Any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.

(2) The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the provider or supplier, A's interest equates to an 8 percent indirect ownership interest in the provider or supplier and must be reported on the enrollment application. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the provider or supplier, B's interest equates to a 4 percent indirect ownership interest in the provider or supplier and need not be reported.

* * * * *

Pattern or practice means:

(1) For purposes of § 424.535(a)(8)(ii), at least three submitted non-compliant claims.

(2) For purposes of § 424.535(a)(14), at least three prescriptions of Part B or Part D drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

(3) For purposes of § 424.535(a)(21), at least three orders, certifications, referrals, or prescriptions of Medicare Part A or B services, items, or drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

* * * * *

Supplier means, for purposes of this subpart, all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

* * * * *

■ 80. Section 424.516 is amended by revising paragraphs (d)(1)(iii) and (e)(1) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(d) * * *

(1) * * *

(iii) A change, addition, or deletion of a practice location.

* * * * *

(e) * * *

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)) or a change, addition, or deletion of a practice location;

* * * * *

■ 81. Section 424.530 is amended by—

■ a. Revising paragraph (a)(1); and

■ b. Adding paragraphs (a)(16), (17), and (18).

The revision and additions read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

* * * * *

(16) *Certain misdemeanors.* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Offenses under paragraph (a)(16)(i) of this section include, but are not limited in scope or severity to, the following:

(A) Fraud or other criminal misconduct involving the provider's or supplier's participation in a Federal or State health care program or the delivery of services or items thereunder.

(B) Assault, battery, neglect, or abuse of a patient (including sexual offenses).

(C) Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(17) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a denial under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502 of this chapter).

(F) Any other information that CMS deems relevant to its determination.

(18) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in § 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

* * * * *

■ 82. Section 424.535 is amended by—

■ a. Revising paragraphs (a)(1) introductory text, (a)(8)(ii) introductory text, and (a)(14)(i) introductory text and (ii) introductory text;

■ b. Adding paragraphs (a)(15) and (16);

■ c. Revising paragraph (a)(17) introductory text;

■ d. Redesignating paragraphs (a)(17)(i) through (vi) as paragraphs (a)(17)(i)(A) through (F);

■ e. Adding paragraph (a)(17)(ii);

■ f. Revising paragraph (a)(21) introductory text;

■ g. Adding paragraph (a)(23); and

■ h. Revising paragraphs (e) and (g).

The additions and revisions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(1) *Noncompliance.* The provider or supplier is determined to not be in compliance with the enrollment requirements described in this title 42, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

* * * * *

(8) * * *

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fails to meet Medicare requirements and that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers, as appropriate or applicable, the following:

* * * * *

(14) * * *

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries, or both, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:

* * * * *

(ii) The pattern or practice of prescribing fails to meet Medicare requirements and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:

* * * * *

(15) *False Claims Act (FCA).* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

(ii) In determining whether a revocation under this paragraph is appropriate, CMS considers the following factors:

(A) The number of provider or supplier actions that the judgment incorporates (for example, the number of false claims submitted).

(B) The types of provider or supplier actions involved.

(C) The monetary amount of the judgment.

(D) When the judgment occurred.

(E) Whether the provider or supplier has any history of final adverse actions (as that term is defined in § 424.502).

(F) Any other information that CMS deems relevant to its determination.

(16) *Certain misdemeanors.* (i) The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has been convicted (as that term is defined in 42 CFR 1001.2) of a misdemeanor under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

(ii) Offenses under paragraph (i) include, but are not limited in scope or severity to, the following:

(A) Fraud or other criminal misconduct involving the provider's or supplier's participation in a Federal or State health care program or the delivery of services or items thereunder.

(B) Assault, battery, neglect, or abuse of a patient (including sexual offenses).

(C) Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(17) *Debt referred to the United States Department of Treasury.* (i) The provider or supplier failed to repay a debt that CMS appropriately referred to the United States Department of Treasury. In determining whether a revocation under this paragraph (a)(17) is appropriate, CMS considers the following factors:

* * * * *

(ii) Paragraph (17)(i) of this paragraph does not apply to the following situations:

(A) The provider's or supplier's Medicare debt has been discharged by a bankruptcy court; or

(B) The administrative appeals process concerning the debt has not been exhausted or the timeframe for filing such an appeal (at the appropriate level of appeal) has not expired.

* * * * *

(21) *Abusive ordering, certifying, referring, or prescribing of Part A or B services, items or drugs.* The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements, and CMS determines that a revocation on this basis is warranted. In determining whether a revocation is warranted, CMS considers the following factors:

* * * * *

(23) *Supplier standard or condition violation.* (i) The independent diagnostic testing facility is non-compliant with any provision in 42 CFR 410.33(g).

(ii) The DMEPOS supplier is non-compliant with any provision in § 424.57(c).

(iii) The opioid treatment program is non-compliant with any provision in § 424.67(b) or (e).

(iv) The home infusion therapy supplier is non-compliant with any provision in § 424.68(c) or (e).

(v) The Medicare diabetes prevention program is non-compliant with any provision in § 424.205(b) or (d).

* * * * *

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 15 days of the revocation notification.

* * * * *

(g) *Effective date of revocation.* (1) Except as described in paragraphs (g)(2) and (g)(3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

(2) Except as described in paragraph (g)(3) of this section, the revocation effective dates in the situations identified in this paragraph (g)(2) are as follows:

(i) For revocations based on a Federal exclusion or debarment, the date of the exclusion or debarment.

(ii) For revocations based on a felony conviction, the date of the felony conviction.

(iii) For revocations based on a State license suspension or revocation, the date of the license suspension or revocation.

(iv) For revocations based on a CMS determination that the provider's or supplier's practice location is non-operational, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

(v) For revocations based on a misdemeanor conviction, the date of the misdemeanor conviction.

(vi) For revocations based on a State license surrender in lieu of further disciplinary action, the date of the license surrender.

(vii) For revocations based on termination from a Federal health care program other than Medicare (for example, Medicaid), the date of the termination.

(viii) For revocations based on termination of a provider agreement under part 489 of this chapter, and as applicable to the type of provider involved, the later of the following:

(A) The date of the provider agreement termination; or

(B) The date that CMS establishes under § 489.55.

(ix) For revocations based on § 424.535(a)(23), the effective dates are as follows:

(A) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(B) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began.

(C) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the effective date is the date of the felony conviction.

(D) For all standard violations not addressed in paragraphs (A) through (C), the effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not.

(3) If the action that resulted in the revocation occurred prior to the effective date of the provider's or supplier's enrollment, the effective date of the revocation is the same as the effective date of enrollment.

* * * * *

■ 83. Section 424.541 is added to read as follows:

§ 424.541 Stay of enrollment.

(a)(1) CMS may stay an enrolled provider's or supplier's enrollment if the provider or supplier:

(i) Is non-compliant with at least one enrollment requirement in Title 42; and.

(ii) Can remedy the non-compliance via the submission of, as applicable to the situation, a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application.

(2) During the period of any stay imposed under this section, the following apply:

(i) The provider or supplier remains enrolled in Medicare;

(ii) Claims submitted by the provider or supplier with dates of service within the stay period will be denied.

(3) A stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter.

(4) CMS notifies the affected provider or supplier in writing of the imposition of the stay.

(b)(1) If a provider or supplier receives written notice from CMS or its contractor that the provider or supplier is subject to a stay under this section, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to the stay as described in paragraph (b) of this section.

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (b)(1) of this section.

(3) Any rebuttal submitted pursuant to paragraph (b) of this section must:

(i) Be in writing.

(ii) Specify the facts or issues about which the provider or supplier disagrees with the stay's imposition and/or the effective date, and the reasons for disagreement.

(iii) Submit all documentation the provider or supplier wants CMS to consider in its review of the stay.

(iv) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(4) The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (b)(1) of this section and fully compliant with all of the requirements of paragraph (b)(3) of this section constitutes a waiver of all rebuttal rights under this section.

(5) Upon receipt of a timely and compliant stay rebuttal, CMS reviews the rebuttal to determine whether the imposition of the stay and/or the effective date thereof are correct.

(6) A determination made under paragraph (b) of this section is not an initial determination under § 498.3(b) and therefore not appealable.

(7) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a stay pending the completion of the review described in paragraph (b)(5) of this section.

(8)(i) Nothing in paragraph (b) of this section requires CMS to delay the imposition of a deactivation or revocation, pending the completion of the review described in paragraph (b)(5) of this section.

(ii)(A) If CMS deactivates the provider or supplier during the stay, any rebuttal to the stay that the provider or supplier submits that meets the requirements of paragraph (b) of this section is combined and considered with the provider's or supplier's rebuttal to the deactivation under § 424.546 if CMS has not yet made a determination on the stay rebuttal pursuant to this section.

(B) In all cases other than that described in paragraph (b)(8)(ii)(A) of this section, a stay rebuttal that was submitted in compliance with the requirements of paragraph (b) of this section is considered separately and independently of any review of any other rebuttal or, for revocations, appeal under 42 CFR part 498.

■ 84. Section 424.555 is amended by revising paragraph (b) to read as follows:

§ 424.555 Payment liability.

* * * * *

(b) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked, or if the provider or supplier is currently under a stay of enrollment. The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 85. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 86. Section 425.20 is amended—

■ a. By revising the definitions of ''Assignable beneficiary'' and ''Assignment window'';

■ b. In the definition of ''At-risk beneficiary'' by—

■ i. Removing the periods at the end of paragraphs (5) and (6), and adding in their place semicolons; and

■ ii. Revising paragraph (7);

■ c. By adding the definitions of ''Beneficiary eligible for Medicare CQMs'' and ''Expanded window for assignment'' in alphabetical order;

■ d. In the definition of ''Experienced with performance-based risk Medicare

ACO initiatives'' by revising paragraph (2);

■ e. In the definition of ''Inexperienced with performance-based risk Medicare ACO initiatives'' by revising paragraph (2);

■ f. In the definition of ''Rural health center'' by—

■ i. Removing the word ''center'' and adding in its place the word ''clinic''; and

■ ii. Removing the phrase ''under § 405.2401(b)'' and adding in its place the phrase ''under § 405.2401(b) of this chapter''.

The revisions and additions read as follows:

§ 425.20 Definitions.

* * * * *

Assignable beneficiary means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c). For performance year 2025 and subsequent performance years, a Medicare fee-for-service beneficiary who does not meet this requirement but who meets both of the following criteria will also be considered an assignable beneficiary—

(1) Receives at least one primary care service with a date of service during a specified 24-month expanded window for assignment from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

(2) Receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

* * * * *

Assignment window means the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both.

At-risk beneficiary * * *

(7) Is entitled to Medicare because of disability; or

* * * * *

Beneficiary eligible for Medicare CQMs means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who is either of the following:

(1) A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

(i) Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

(ii) Had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or certified nurse specialist.

(2) A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

* * * * *

Expanded window for assignment means the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

Experienced with performance-based risk Medicare ACO initiatives * * *

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

* * * * *

Inexperienced with performance-based risk Medicare ACO initiatives * * *

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

* * * * *

■ 87. Section 425.106 is amended by revising paragraph (c)(5) to read as follows:

§ 425.106 Shared governance.

* * * * *

(c) * * *

(5) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraph (c)(2) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

* * * * *

■ 88. Section 425.204 is amended by revising paragraph (c)(3) to read as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(3) If an ACO requests an exception to the governing body requirement in § 425.106(c)(2), the ACO must describe—

(i) Why it seeks to differ from the requirement; and

(ii) How the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

* * * * *

■ 89. Section 425.302 is amended by revising paragraph (a)(3)(iii) to read as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iii) For performance years starting on January 1, 2019 through 2023, the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

■ 90. Section 425.308 is amended by adding paragraph (b)(9) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(9) The number of MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this chapter) participating in the ACO that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual,

group, virtual group, or APM entity level as set forth in § 425.507.

* * * * *

■ 91. Section 425.316 is amended by revising paragraphs (e)(2) introductory text and (e)(2)(i) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(e) * * *

(2) If CMS determines that an ACO participating in advance investment payments became experienced with performance-based risk Medicare ACO initiatives during its first or second performance year of its agreement period or that the ACO became a high revenue ACO during any performance year of its agreement period, CMS—

(i) Will cease payment of advance investment payments no later than the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

* * * * *

■ 92. Section 425.400 is amended—

■ a. By revising paragraph (a)(2)(ii);

■ b. In paragraph (a)(3)(i), by removing the phrase ''most recent 12 months'' and adding in its place the phrase ''most recent 12 or 24 months, as applicable,'';

■ c. By revising paragraph (c)(1)(vii) introductory text;

■ d. By adding paragraph (c)(1)(viii); and

■ e. By revising paragraphs (c)(2)(i) introductory text and (c)(2)(ii).

The revisions and addition read as follows:

§ 425.400 General.

(a) * * *

(2) * * *

(ii) Assignment will be updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404.

* * * * *

(c) * * *

(1) * * *

(vii) For the performance year starting on January 1, 2023 as follows:

* * * * *

(viii) For the performance year starting on January 1, 2024, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*4*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*5*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*6*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*7*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(viii)).

(*8*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*9*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*10*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*11*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*12*) 99439 (code for non-complex chronic care management).

(*13*) 99457 and 99458 (codes for remote physiologic monitoring).

(*14*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*15*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*16*) 99495 and 99496 (codes for transitional care management services).

(*17*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(*18*) 9X015, 9X016, and 9X017 (codes for caregiver training services).

(B) HCPCS codes:

(*1*) G0101 (code for cervical or vaginal cancer screening).

(*2*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*3*) G0402 (code for the Welcome to Medicare visit).

(*4*) G0438 and G0439 (codes for the annual wellness visits).

(*5*) G0442 (code for alcohol misuse screening service).

(*6*) G0443 (code for alcohol misuse counseling service).

(*7*) G0444 (code for annual depression screening service).

(*8*) G0463 (code for services furnished in ETA hospitals).

(*9*) G0506 (code for chronic care management).

(*10*) G2010 (code for the remote evaluation of patient video/images).

(*11*) G2012 and G2252 (codes for virtual check-in).

(*12*) G2058 (code for non-complex chronic care management).

(*13*) G2064 and G2065 (codes for principal care management services).

(*14*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*15*) G2211 (code for complex evaluation and management services add-on).

(*16*) G2214 (code for psychiatric collaborative care model).

(*17*) G3002 and G3003 (codes for chronic pain management).

(*18*) GXXX1 and GXXX2 (codes for community health integration services).

(*19*) GXXX3 and GXXX4 (codes for principal illness navigation services).

(*20*) GXXX5 (code for social determinants of health risk assessment services).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(viii)(A) of this section or a HCPCS code specified in paragraph (c)(1)(viii)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2) * * *

(i) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, when the assignment window or applicable expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

* * * * *

(ii) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, the additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window or applicable expanded window for assignment (as defined in § 425.20), when the assignment window or applicable expanded window for assignment includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

■ 93. Section 425.402 is amended—
■ a. By revising paragraph (b)(1);
■ b. By adding paragraph (b)(5);
■ c. By revising paragraph (c) introductory text; and
■ d. In paragraph (e)(2)(ii)(A), by removing the reference ''§ 425.400(a)(4)(ii)'' and adding in its place the reference ''§ 425.226(a)(1)''.

The revisions and addition read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(b) * * *

(1) Identify all beneficiaries that had at least one primary care service during the applicable assignment window with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

* * * * *

(5) For performance year 2025 and subsequent performance years, CMS employs the following third step to assign Medicare fee-for-service beneficiaries who were not identified by the criterion specified in paragraph (b)(1) of this section:

(i) Identify all beneficiaries who had at least one primary care service with a non-physician ACO professional in the ACO during the applicable assignment window.

(ii) For the beneficiaries identified in paragraph (b)(5)(i) of this section, identify those beneficiaries that had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iii) Identify all primary care services furnished to beneficiaries identified in paragraph (b)(5)(ii) of this section by ACO professionals in the ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in paragraph (c) of this section during the applicable expanded window for assignment.

(iv) A beneficiary identified in paragraph (b)(5)(ii) of this section is assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in paragraph (c) of this section, or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations as specified in paragraph (c) of this section, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(A) ACO professionals in any other ACO; or

(B) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(c) ACO professionals considered in the second and third step of the assignment methodology in paragraphs (b)(4) and (5) of this section include physicians who have one of the following primary specialty designations:

* * * * *

■ 94. Section 425.506 is amended by revising paragraph (f) introductory text to read as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(f) For performance years starting on January 1, 2019 through 2023, ACOs in a track that—

* * * * *

■ 95. Section 425.507 is added to subpart F to read as follows:

§ 425.507 Incorporating promoting interoperability requirements related to the Quality Payment Program for performance years beginning on or after January 1, 2024.

(a) For performance years beginning on or after January 1, 2024, unless otherwise excluded under paragraph (b) of this section, all MIPS eligible clinicians, Qualifying APM Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) (each as defined at § 414.1305 of this chapter) participating in the ACO must satisfy all of the following:

(1) Report the MIPS Promoting Interoperability performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following—

(i) All MIPS eligible clinicians, QPs, and Partial QPs participating in the ACO as an individual, group, or virtual group; or

(ii) The ACO as an APM entity.

(2) Earn a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

(b) A MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity may be excluded from the requirements set forth in paragraph (a) of this section if the MIPS eligible clinician, QP, Partial QP, or ACO as an APM entity—

(1) Does not exceed the low volume threshold set forth at § 414.1310(b)(1)(iii) of this chapter;

(2) Is an eligible clinician as defined at § 414.1305 of this chapter who is not a MIPS eligible clinician and has opted to voluntarily report measures and activities for MIPS as set forth in § 414.1310(b)(2) of this chapter; or

(3) Has not earned a performance category score for the MIPS Promoting Interoperability performance category because the MIPS Promoting Interoperability performance category has been reweighted in accordance with applicable policies set forth at § 414.1380(c)(2) of this chapter.

■ 96. Section 425.512 is amended—
■ a. By revising paragraph (a)(2);
■ b. In paragraph (a)(5)(i) introductory text, by removing the phrase ''paragraph (a)(2) of this section'' and adding in its place the phrase ''paragraphs (a)(2) and (a)(7) of this section'';
■ c. By revising paragraph (a)(5)(i)(A)(*2*), (a)(5)(iii)(A) and (B);
■ d. By adding paragraph (a)(7);
■ e. In paragraph (b)(1)—
■ i. By adding a new first sentence;
■ ii. By removing the reference ''paragraph (b)(2)'' and adding in its place the reference ''paragraph (b)(3)'';
■ f. By redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;
■ g. By adding new paragraph (b)(2);
■ h. By revising the newly redesignated paragraph (b)(3)(ii)(B);
■ i. In newly redesignated paragraph (b)(3)(iii), by removing the phrase ''paragraph (b)(2)(ii) of this section'' and adding in its place the phrase ''paragraph (b)(3)(ii) of this section'';
■ j. By revising newly redesignated paragraph (b)(3)(iv)(A);
■ k. In newly redesignated paragraph (b)(3)(iv)(B), by removing the phrase ''paragraph (b)(2)(iv)(A) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv)(A) of this section'';
■ l. In newly redesignated paragraph (b)(3)(v)—
■ i. By removing the phrase ''paragraph (b)(2)(iv)(B) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv)(B) of this section'';
■ ii. By removing the phrase ''paragraph (b)(2)(iii) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iii) of this section'';
■ iii. By removing the phrase ''paragraph (b)(2)(iv) of this section'' and adding in its place the phrase ''paragraph (b)(3)(iv) of this section'';
■ m. In newly redesignated paragraph (b)(4) introductory text, by removing the

phrase ''paragraphs (b)(1) and (b)(2) of this section'' and adding in its place the phrase ''paragraphs (b)(1) through (b)(3) of this section''; and

■ n. By revising paragraph (c)(3).

The revisions and additions read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(2) For the first performance year of an ACO's first agreement period under the Shared Savings Program, the ACO will meet the quality performance standard if it meets the requirements under this paragraph (a)(2).

(i) For performance years 2022 and 2023. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey, for the applicable performance year.

(ii) For performance year 2024. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

(iii) For performance year 2025 and subsequent performance years. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter on the three eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

* * * * *

(5) * * *

(i) * * *

(A) * * *

(*2*) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

* * * * *

(iii) * * *

(A) For performance year 2024, the ACO does not report any of the ten CMS Web Interface measures, any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this chapter) under the APP.

(B) For performance year 2025 and subsequent years, the ACO does not report any of the three eCQMs/MIPS CQMs/Medicare CQMs and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this chapter) under the APP.

* * * * *

(7) For performance years 2024 and subsequent performance years, if an ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this chapter for each measure in the APP measure set and receiving a MIPS quality performance category score as described at § 414.1380(b)(1) of this chapter, and the ACO's total available measure achievement points used to calculate the ACO's MIPS quality performance category score is reduced under § 414.1380(b)(1)(vii)(A) of this chapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(b) * * *

(1) For performance year 2023. * * *

(2) For performance year 2024 and subsequent performance years. For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this chapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this chapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(3) of this section. The sum of these values may not exceed 100 percent.

(3) * * *

(ii) * * *

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

* * * * *

(iv) * * *

(A) (*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(3)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance year 2024 and subsequent performance years, the proportion of the ACO's assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

* * * * *

(c) * * *

(3) If CMS determines the ACO meets the requirements of paragraph (c)(1) of this section and the ACO reports quality data via the APP, CMS calculates the ACO's quality score as follows:

(i) For performance years 2021 and 2022, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality

performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2023, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(iii) For performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets the data completeness requirement at § 414.1340 of this chapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this chapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

§ 425.600 [Amended]

■ 97. Amend § 425.600 in paragraph (f)(4)(ii) by removing the reference ''425.656(d)'' and adding in its place the reference ''425.656(e)''.

§ 425.601 [Amended]

■ 98. Amend § 425.601 in paragraph (a) introductory text by removing the reference ''§ 425.226(a)(1)'' and adding in its place the reference ''§ 425.400(a)(4)(ii)''.

§ 425.611 [Amended]

■ 99. Amend § 425.611 in paragraph (c)(2)(iii) by removing the reference ''§ 425.652(a)(8)(iv)'' and adding in its place the reference ''§ 425.658(c)(1)(ii)''.

■ 100. Section 425.630 is amended—

■ a. By revising paragraphs (b)(2) and (3), (e)(3), (f) introductory text, and (g)(4);

■ b. In paragraph (h)(1)(i), by removing ''or'' at the end of the paragraph;

■ c. In paragraph (h)(1)(ii), by removing ''.'' at the end of the paragraph, and adding in its place ''; or''; and

■ d. By adding paragraphs (h)(1)(iii) and (i).

The revisions and additions read as follows:

§ 425.630 Option to receive advance investment payments.

* * * * *

(b) * * *

(2) CMS has determined that the ACO is eligible to participate in the Shared Savings Program.

(3) The ACO is inexperienced with performance-based risk Medicare ACO initiatives during its first two performance years and participates in the BASIC track's glide path as follows:

(i) For performance year 1, the ACO must participate in Level A of the BASIC track's glide path.

(ii) For performance year 2, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)) or Level B.

(iii) For performance years 3 through 5, the ACO may participate in Level A of the BASIC track's glide path (in accordance with § 425.600(a)(4)(i)(C)(*3*)), or Levels B through E.

* * * * *

(e) * * *

(3) *Duration for spending payments.* An ACO may spend an advance investment payment over its entire agreement period. An ACO must repay to CMS any unspent funds remaining at the end of the ACO's agreement period, except if the ACO terminated its current participation agreement under § 425.220 beginning with the third or fourth performance year and immediately enters a new agreement period to continue its participation in the Shared Savings Program, the ACO must spend its advance investment payments within 5 performance years of when it first received advance investment payments and repay to CMS any unspent funds remaining at the end of that fifth performance year.

* * * * *

(f) *Payment methodology.* An ACO receives two types of advance investment payments: a one-time payment of $250,000 and quarterly payments calculated pursuant to the methodology defined in paragraph (f)(2) of this section. CMS notifies in writing each ACO of its determination of the amount of advance investment payment and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS does not make any advance investment payment, the notice will specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

* * * * *

(g) * * *

(4) If an ACO terminates its participation agreement during the agreement period in which it received an advance investment payment, the ACO must repay all advance investment payments it received, unless the ACO terminated its current participation agreement under § 425.220 at the end of performance year 2 or later during the agreement period in which it received advance investment payments and immediately enters a new agreement period to continue its participation in the program. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

* * * * *

(h) * * *

(1) * * *

(iii) Voluntarily terminates its participation agreement in accordance with § 425.220(a).

* * * * *

(i) *Reporting information on advance investment payments.* The ACO must report information on its receipt of and use of advance investment payments, as follows:

(1) The ACO must publicly report information about the ACO's use of advance investment payments for each performance year, in accordance with § 425.308(b)(8).

(2) In a form and manner and by a deadline specified by CMS, the ACO must report to CMS the same information it is required to publicly report under § 425.308(b)(8).

§ 425.650 [Amended]

■ 101. Amend § 425.650 in paragraph (a) by removing the references ''§§ 425.601, 425.602, and 425.603'' and adding in their place the references ''§§ 425.601, 425.602, 425.603, and 425.659''.

■ 102. Section 425.652 is amended—

■ a. In paragraph (a) introductory text, by removing the reference ''§ 425.226(a)(1)'' and adding in its place the reference ''§ 425.400(a)(4)(ii)'';

■ b. By revising paragraphs (a)(5)(v)(A), (a)(8), (a)(9) introductory text, and (a)(9)(ii);

■ c. In paragraph (a)(9)(iv), by removing the reference ''§ 425.400(a)(4)(ii)'' and adding in its place the reference ''§ 425.226(a)(1)'';

■ d. In paragraph (a)(9)(v), by removing the phrase '', or a combination of these two adjustments'';

■ e. By adding paragraphs (a)(9)(vi) and (b)(2)(ii)(C); and

■ f. By revising paragraph (b)(2)(iv)(A).

The revisions and additions read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) * * *

(5) * * *

(v) * * *

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(8) Except as provided in paragraph (a)(8)(iii) of this section, adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(i) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(ii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single per capita value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(iii) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single per capita value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(iv) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

(A) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) A prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(v) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(9) For the first performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under § 425.659, and for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315. To adjust the benchmark, CMS does the following:

* * * * *

(ii) Redetermines the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(vi) Redetermines factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with § 425.659(b)(1).

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(C) Multiply the growth rate calculated in this paragraph (b)(2)(ii) by a regional risk score growth cap adjustment factor computed as described in § 425.655.

* * * * *

(iv) * * *

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

■ 103. Section 425.654 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 425.654 Calculating county expenditures and regional expenditures.

(a) * * *

(1) * * *

(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

■ 104. Section 425.655 is added to subpart G to read as follows:

§ 425.655 Calculating the regional risk score growth cap adjustment factor.

(a) *General.* This section describes the methodology for calculating the regional risk score growth cap adjustment factor that will be applied to the regional growth rate component of the three-way blend used to update the historical benchmark as described in § 425.652(b) for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Calculating county risk scores.* CMS does all of the following to determine county prospective HCC and demographic risk scores for use in calculating the ACO's regional risk scores:

(1) Determines average county prospective HCC and demographic risk scores for the assignable population of beneficiaries in each county in the ACO's regional service area. The assignable population of beneficiaries is identified for the relevant benchmark or performance year using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(2) Makes separate risk score calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) *Calculating regional risk scores.* CMS calculates an ACO's regional prospective HCC and demographic risk scores by:

(1) Weighting the county-level risk scores determined under paragraph (b) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (c)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area.

(d) *Determining aggregate growth in regional risk scores.* CMS determines aggregate growth in regional prospective HCC and demographic risk scores by:

(1) Determining growth in regional prospective HCC and demographic risk scores determined in paragraph (c) of this section (expressed as a ratio of the performance year regional risk score to the BY3 regional risk score) for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Determines the aggregate growth in regional risk scores by calculating a weighted average of the growth in regional prospective HCC risk scores or demographic risk scores, as applicable, across the populations described in paragraph (d)(1) of this section. When calculating the weighted average growth in prospective HCC risk scores or demographic risk scores, as applicable, the weight applied to the growth in risk scores for each Medicare enrollment type is equal to the product of the ACO's regionally adjusted historical benchmark expenditures for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

(e) *Determining the cap on regional risk score growth.* CMS determines the cap on regional prospective HCC risk score growth by:

(1) Computing the sum of the aggregate growth in regional demographic risk scores as determined in paragraph (d)(2) of this section and 3 percentage points.

(2) Calculating the ACO's aggregate market share by calculating the weighted average of the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the performance year as determined in § 425.652(b)(2)(iv) across the populations described in § 425.652(b)(1). In calculating this weighted average, the weight applied to the share for each Medicare enrollment type is equal to the ACO's performance year assigned beneficiary person years for that enrollment type.

(3) Adding to the sum computed in paragraph (e)(1) of this section an amount equal to the product of:

(i) The ACO's aggregate market share as determined in paragraph (e)(2) of this section.

(ii) The difference between the aggregate growth in regional prospective HCC risk scores as determined in paragraph (d)(2) of this section and the sum determined in paragraph (e)(1) of this section. This difference is subject to a floor of zero.

(f) *Determining the regional risk score growth cap adjustment factor.* CMS determines the regional risk score growth cap adjustment factor for each Medicare enrollment type to be applied in calculating the regional growth rate described in § 425.652(b) by comparing the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section and, if applicable, the growth in regional prospective HCC risk scores for individual Medicare enrollment types as determined in paragraph (d)(1) of this section with the cap determined in paragraph (e) of this section.

(1) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor equal to 1 for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) If the aggregate growth in regional prospective HCC risk scores determined in paragraph (d)(2) of this section exceeds the cap determined in paragraph (e) of this section, CMS will compare the growth in regional prospective HCC risk scores for each Medicare enrollment type as determined in paragraph (d)(1) of this section with the cap on regional risk score growth determined in paragraph (e) of this section.

(i) If the growth in regional prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section does not exceed the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor equal for that enrollment type equal to 1.

(ii) If the growth in regional prospective HCC risk scores determined in paragraph (d)(1) for the enrollment type exceeds the cap on regional risk score growth determined in paragraph (e) of this section, CMS will set the regional risk score growth cap adjustment factor for that enrollment type equal to the growth in regional

prospective HCC risk scores for the enrollment type determined in paragraph (d)(1) of this section divided by the cap on regional risk score growth determined in paragraph (e) of this section.

■ 105. Section 425.656 is amended—

■ a. By revising paragraph (b)(3);

■ b. In paragraph (c)(2), by removing the phrase ''paragraph (d) of this section'' and adding in its place the phrase ''paragraph (e) of this section'';

■ c. By redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively;

■ d. By adding new paragraph (d);

■ e. In newly redesignated paragraph (e)(5)(ii), by removing the phrase ''paragraph (d)(5)(i) of this section'' and adding in its place the phrase ''paragraph (e)(5)(i) of this section'';

■ f. In newly redesignated paragraph (e)(5)(iv), by removing the phrase ''paragraphs (d)(1) through (3)'' and adding in its place the phrase ''paragraphs (e)(1) through (3)''; and

■ g. In newly redesignated paragraph (f) introductory text, by removing the phrase ''paragraphs (b) through (d)'' and adding in its place the phrase ''paragraphs (b) through (e)''.

The revision and addition read as follows:

§ 425.656 Calculating the regional adjustment to the historical benchmark.

* * * * *

(b) * * *

(3) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population for BY3 and the assignable population of beneficiaries for the ACO's regional service area for BY3. The assignable population of beneficiaries is identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

* * * * *

(d) *Expression of the regional adjustment as a single value.* (1) CMS expresses the regional adjustment as a single value by taking a person-year weighted average of the Medicare enrollment type-specific regional adjustment values determined in paragraph (c) of this section.

(2) CMS uses the regional adjustment expressed as a single value for purposes of determining the adjustment, if any, that will be applied to the benchmark in accordance with § 425.652(a)(8).

* * * * *

■ 106. Section 425.658 is amended—

■ a. In paragraph (b)(3)(i), by removing the sentence ''The ACO will receive the regional adjustment to its benchmark as described in § 425.656.'';

■ b. By redesignating paragraph (c) as paragraph (d);

■ c. By adding new paragraph (c);

■ d. By revising newly redesignated paragraph (d); and

■ e. By adding new paragraph (e).

The revision and additions read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

* * * * *

(c) *Calculate the per capita savings adjustment.*

(1) If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

(i) 50 percent of the pro-rated average per capita amount computed in paragraph (b)(3)(ii) of this section.

(ii) 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(2) [Reserved]

(d) *Applicability of the prior savings adjustment.* CMS compares the per capita prior savings adjustment determined in paragraph (c)(1) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

(e) *Recalculation of the prior savings adjustment during an agreement period.*

(1) The ACO's prior savings adjustment is recalculated for changes to the ACO's savings or losses for a performance year used in the prior savings adjustment calculation in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

(2) For a new ACO identified as a re-entering ACO, the prior savings adjustment is recalculated for changes to savings or losses for a performance year used in the prior savings adjustment calculation, if the savings or losses of the ACO in which the majority of the new ACO's participants were participating change in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315.

■ 107. Section 425.659 is added to subpart G to read as follows:

§ 425.659 Calculating risk scores used in Shared Savings Program benchmark calculations.

(a) *General.* CMS accounts for differences in severity and case mix of the ACO's assigned beneficiaries and assignable beneficiaries (as defined under § 425.20) in calculations used in establishing, adjusting and updating the ACO's historical benchmark.

(b) *Prospective Hierarchical Condition Category (HCC) risk score calculation.* In determining Medicare FFS beneficiary prospective HCC risk scores for a performance year and each benchmark year of the ACO's agreement period, CMS does the following:

(1) CMS specifies the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores for Medicare FFS beneficiaries (as defined under § 425.20) for use in Shared Savings Program calculations as follows:

(i) In calculating risk scores for Medicare FFS beneficiaries for a performance year, CMS applies the CMS–HCC risk adjustment methodology applicable for the corresponding calendar year.

(ii) For agreement periods beginning before January 1, 2024, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to benchmark year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(iii) For agreement periods beginning on January 1, 2024, and in subsequent years, CMS applies the CMS–HCC risk adjustment methodology for the calendar year corresponding to the performance year, as specified under paragraph (b)(1)(i) of this section, in calculating risk scores for Medicare FFS beneficiaries for each benchmark year of the agreement period.

(2) CMS does the following to calculate the prospective HCC risk scores identified in paragraph (b)(1) of this section for a benchmark or performance year:

(i) Removes the Medicare Advantage coding intensity adjustment, if applicable.

(ii) Renormalizes prospective HCC risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) based on a national assignable FFS population for

the relevant benchmark or performance year.

(iii) Calculates the average prospective HCC risk score by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries).

■ 108. Section 425.702 is amended—

■ a. In paragraph (c)(1)(ii) introductory text, by removing the phrase ''process development'' and adding in its place the phrase ''protocol development'';

■ b. By revising paragraph (c)(1)(ii)(A)(*3*); and

■ c. By adding paragraph (c)(1)(iii).

The revision and addition read as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(A) * * *

(*3*) Beneficiary identifier.

* * * * *

(iii) For performance year 2024 and subsequent performance years, at the beginning of the quality submission period, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, protocol development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

(A) The following information is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Beneficiary name.

(*2*) Date of birth.

(*3*) Beneficiary identifier.

(*4*) Sex.

(B) Information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available to ACOs regarding beneficiaries eligible for Medicare CQMs as defined at § 425.20:

(*1*) Demographic data such as enrollment status.

(*2*) Health status information such as risk profile and chronic condition subgroup.

(*3*) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 109. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 110. Section 455.416 is amended by revising paragraph (c) to read as follows:

§ 455.416 Termination or denial of enrollment.

* * * * *

(c) Must deny enrollment or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act and under the Medicaid program or CHIP of any other State, and is currently included in the termination database under § 455.417.

* * * * *

■ 111. Section 455.417 is added to read follows:

§ 455.417 Termination periods and termination database periods.

(a)(1) Subject to paragraph (c) of this section, a provider remains in the termination notification database referenced in section 1902(ll) of the Act for a period that is the lesser of:

(i) The length of the termination period imposed by the State that initially terminated the provider or the reenrollment bar (as described in § 424.535(c) of this chapter) imposed by the Medicare program in the case of a Medicare revocation; or

(ii) 10 years (for those Medicaid or CHIP terminations that are greater than 10 years).

(2) All other State Medicaid agencies or CHIPs must terminate or deny the provider from their respective programs (pursuant to § 455.416(c)) for at least the same length of time as the termination database period described in paragraph (a)(1) of this section.

(b)(1) Nothing in paragraph (a) of this section prohibits:

(i) The initially terminating State from imposing a termination period of greater than 10 years consistent with that State's laws, or

(ii) Another State from terminating the provider, based on the original State's termination, for a period:

(A) Of greater than 10 years; or

(B) That is otherwise longer than that imposed by the initially terminating State.

(2) The period established under paragraph (b)(1)(ii) of this section must be no shorter than the period in which the provider is to be included in the termination database under paragraph (a) of this section.

(c)(1) If the initially terminating State agency or the Medicare program reinstates the provider prior to the end of the termination period originally imposed by the initially terminating State agency or Medicare, CMS removes the provider from the termination database after the reinstatement has been reported to CMS.

(2) If the provider is removed from the database pursuant to paragraph (c)(1), CMS may immediately reinclude the provider in the database (with no interval between the two periods) if a basis for doing so exists under part 455 or 424 of this chapter.

(d) For purposes of this section only, terminations under § 455.416(c) are not considered ''for cause'' terminations and therefore need not be reported to CMS for inclusion in the termination database.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 112. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 113. Section 489.30 is amended by—

■ a. Revising paragraph (b)(1); and

■ b. Adding paragraphs (b)(6) and (7).

The revision and additions read as follows:

§ 489.30 Allowable charges: Deductibles and coinsurance.

* * * * *

(b) * * *

(1) The basic allowable charges are the Part B annual deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible, except as specified in paragraphs (b)(6) and (7) of this section.

* * * * *

(6) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), including a selected drug (as defined in section 1192(c) of the Act), furnished on or after April 1, 2023, in a calendar quarter in which the payment amount for such drug as specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, exceeds the inflation-adjusted amount (as defined in section 1847A(i)(3)(C) of the Act) for such drug, the basic allowable charges are the Part B annual deductible and 20 percent of the of the inflation-adjusted payment amount for the rebatable drug in excess of that deductible, which is applied as a percent to the payment amount for such calendar quarter.

(7) In the case of insulin furnished on or after July 1, 2023 through an item of durable medical equipment covered under section 1861(n) of the Act, the coinsurance amount shall not exceed $35 for a month's supply of such insulin

each calendar month. This limitation on the coinsurance amount shall apply for the duration of the calendar month in which the date of service (or services) occurs. In addition, the coinsurance amount shall not exceed $105.00 for three months' supply of insulin. This limitation on the coinsurance amount shall apply for the duration of the calendar month in which the date of service (or services) occurs and the two following calendar months.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 114. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

■ 115. Section 491.2 is amended by—
■ a. Adding the definitions of ''Certified nurse-midwife (CNM)'', ''Clinical psychologist (CP)'', ''Clinical social worker'', ''Marriage and family therapist'', and ''Mental health counselor'' in alphabetical order; and
■ b. Revising the definition of ''Nurse practitioner''.

The additions and revisions read as follows:

§ 491.2 Definitions.

* * * * *

Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at § 410.77(a) of this chapter.

Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.

Clinical social worker means an individual who meets the applicable education, training, and other requirements at § 410.73(a) of this chapter.

* * * * *

Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at 410.53 of this chapter.

Mental health counselor means an individual who meets the applicable education, training, and other requirements at 410.54 of this chapter.

Nurse practitioner means a person who meets the applicable State requirements governing the qualifications for nurse practitioners, and who meets at least one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

* * * * *

■ 116. Section 491.8 is amended by revising paragraphs (a)(3) and (6) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(3) The physician assistant, nurse practitioner, certified nurse-midwife, clinical social worker,-clinical psychologist, marriage and family therapist, or mental health counselor member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

* * * * *

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or a mental health counselor is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 117. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 118. Section 495.4 is amended in the definition of ''Certified electronic health record technology (CEHRT)'' by revising paragraph (2) introductory text to read as follows:

§ 495.4 Definitions.

* * * * *

Certified electronic health record technology (CEHRT) * * *

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315—

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 119. The authority citation for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 120. In § 498.2 amend the definition of ''Supplier'' by revising paragraph (6) to read as follows:

§ 498.2 Definitions.

* * * * *

Supplier * * *

(6) For purposes of this part, a physical therapist in private practice, an occupational therapist in private practice, or a speech-language pathologist.

* * * * *

PART 600—ADMINISTRATION, ELIGIBILITY, ESSENTIAL HEALTH BENEFITS, PERFORMANCE STANDARDS, SERVICE DELIVERY REQUIREMENTS, PREMIUM AND COST SHARING, ALLOTMENTS, AND RECONCILIATION

■ 121. The authority citation for part 600 continues to read as follows:

Authority: Section 1331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 State. 1029).

■ 122. Revise § 600.125 to read as follows:

§ 600.125 Revisions to a certified BHP Blueprint.

(a) *Submission of revisions.* A State may seek to revise its certified Blueprint in whole or in part at any time through the submission of a revised Blueprint to HHS. A State must submit a revised Blueprint to HHS whenever necessary to reflect—

(1) Changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in the certified Blueprint;

(2) Significant changes that alter core program operations under 600.145(f) or the BHP benefit package; or

(3) Changes to enrollment, disenrollment, and verification policies described in the certified Blueprint.

(b) *Submission and effective dates.* The effective date of a revised Blueprint may not be earlier than the first day of the quarter in which an approvable

revision is submitted to HHS. A revised Blueprint is deemed received when HHS receives an electronic copy of a cover letter signed by the Governor or Governor's designee and a copy of the currently approved Blueprint with proposed changes in track changes.

(c) *Timing of HHS review.* (1) A revised Blueprint will be deemed approved unless HHS, within 90 calendar days after receipt of the revised Blueprint, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of additional information it needs in order to make a final determination.

(2) If HHS requests additional information, the 90-day review period for HHS action on the revised Blueprint—

(i) Stops on the day HHS sends a written request for additional information or the next business day if the request is sent on a Federal holiday or weekend; and

(ii) Resumes on the next calendar day of the original 90-day review period after HHS receives an a complete response from the State of all the requested additional information, unless the information is received after 5 p.m. eastern standard time on a day prior to a non-business day or any time on a non-business day, in which case the review period resumes on the following business day.

(3) The 90-day review period cannot stop or end on a non-business day. If the 90th calendar day falls on a non-business day, HHS will consider the 90th day to be the next business day.

(4) HHS may send written notice of its need for additional information as many times as necessary to obtain the complete information necessary to review the revised Blueprint.

(5) HHS may disapprove a Blueprint that is not consistent with section 1331 of the ACA or the regulations set forth in this Part at any time during the review process, including when the 90-day review clock is stopped due to a request for additional information.

(d) *Continued operation.* The State is responsible for continuing to operate under the terms of the existing certified Blueprint until and unless—

(1) The State adopts a revised Blueprint by obtaining approval by HHS under this section;

(2) The State follows the procedures described in § 600.140(a) for terminating a BHP;

(3) The State follows the procedures described in § 600.140(b) for suspending a BHP;

(4) The Secretary withdraws certification of a BHP under 600.142.

(e) *Withdrawal of a revised Blueprint.* A State may withdraw a proposed Blueprint revision during HHS' review if the State has not yet implemented the proposed changes and provides written notice to HHS.

(f) *Reconsideration of decision.* HHS will accept a State request for reconsideration of a decision not to certify a revised Blueprint and provide an impartial review against the standards for certification if requested.

(g) *Public health emergency.* For the Public Health Emergency, as defined in § 400.200 of this chapter, the State may submit to the Secretary for review and certification a revised Blueprint, in the form and manner specified by HHS, that makes temporary significant changes to its BHP that are directly related to the Public Health Emergency and would increase enrollee access to coverage. Such revised Blueprints may have an effective date retroactive to the first day of the Public Health Emergency and through the last day of the Public Health Emergency, or a later date if requested by the State and certified by HHS. Such revised Blueprints are not subject to the public comment requirements under § 600.115(c).

■ 123. Section 600.135 is amended by revising the section heading and paragraph (a) to read as follows:

§ 600.135 Notice and timing of HHS action on an initial BHP Blueprint submission.

(a) *Timely response.* HHS will act on all initial Blueprint certification requests in a timely manner.

* * * * *

■ 124. Section 600.140 is amended by adding introductory text and paragraphs (b) through (d) to read as follows:

§ 600.140 State termination or suspension of a BHP.

A State that no longer wishes to operate a BHP may terminate or suspend its BHP:

* * * * *

(b) If a State decides to suspend its BHP, or to request an extension of a previously-approved suspension, the State must:

(1) Submit to the Secretary a suspension application or a suspension extension application, as applicable. The suspension or suspension extension application must:

(i) Demonstrate that the benefits BHP-eligible individuals will receive during the suspension are equal to the benefits provided under the certified BHP Blueprint in effect on the effective date of suspension;

(ii) Demonstrate that the median actuarial value of the coverage provided to the BHP-eligible individuals during the suspension is no less than the median actuarial value of the coverage under the certified BHP Blueprint in effect on the effective date of suspension;

(iii) Demonstrate that the premiums imposed on BHP-eligible individuals during the suspension are no higher than the premiums charged under the certified BHP Blueprint in effect on the effective date of suspension, except that premiums imposed during the suspension may be adjusted for inflation, as measured by the Consumer Price Index;

(iv) Demonstrate that the eligibility criteria for coverage during the suspension is not more restrictive than the criteria described in § 600.305;

(v) Describe the period, not to exceed 5 years, that the State intends to suspend its BHP or to extend a previously-approved suspension;

(vi) Be submitted at least 9 months in advance of the proposed effective date of the suspension or extension, except for States seeking to suspend a BHP in the first plan year that begins following publication of this rule must submit an application within 30 days of publication of this rule; and

(vii) Include an evaluation of the coverage provided to BHP eligible individuals during the suspension period, if the State is seeking an extension.

(2) Resolve concerns expressed by HHS and obtain approval by the Secretary of the suspension or suspension extension application. Suspensions may not be in effect prior to approval by HHS, except for States seeking to suspend a BHP in the first plan year that begins following publication of this rule.

(3) At least 90 days prior to the effective date of the suspension, submit written notice to all enrollees and participating standard health plan offerors that it intends to suspend the program, if the enrollees will experience a change in coverage, or standard health plan offerors will experience a change in the terms of coverage. The notices to enrollees must include information regarding the State's assessment of their eligibility for all other insurance affordability programs in the State. Notices must meet the accessibility and readability standards at 45 CFR 155.230(b).

(4) Within 12 months of the suspension effective date, submit to HHS the data required by § 600.610 needed to complete the financial reconciliation process with HHS.

(5) Submit the annual report required by § 600.170(a)(2), describing the

balance of the trust fund, and any interest accrued on such amount.

(6) Annually, remit to HHS any interest that has accrued on the balance of the BHP trust fund during the suspension period in the form and manner specified by HHS.

(7) At least 9 months before the end of the suspension period described in paragraph (b)(1)(iv) of this section, or earlier date elected by the State, the State must submit to HHS a transition plan that describes how the State will be reinstate its BHP consistent with the requirements of this part, or terminate the program in accordance with paragraph (a) of this section. The State must meet the noticing requirements of paragraph (b)(3) of this section prior to terminating or reinstating the BHP.

(c) The State cannot implement the suspension or extension of the suspension without prior approval by the Secretary.

(d) The Secretary may withdraw approval of the suspension plan, if the terms of paragraph (b) of this section are not met, if the State ends implementation of the alternative coverage program for any reason, or if HHS finds significant evidence of beneficiary harm, financial malfeasance, fraud, waste, or abuse by the BHP agency or the State consistent with § 600.142 of this part. If HHS withdraws the approved suspension plan, the State must reinstate its BHP under the terms of this Part, or terminate the program under paragraph (a) of this section.

(1) Withdrawal of approval of a suspension under this section must occur only after the Secretary provides the State with notice of the findings upon which the Secretary is basing the withdrawal; a reasonable period for the State to address the finding; and an opportunity for a hearing before issuing a final finding.

(2) The Secretary must make every reasonable effort to work with the State to resolve proposed findings without withdrawing approval of a suspension and in the event of a decision to withdraw approval, will accept a request from the State for reconsideration.

(3) The effective date of an HHS determination withdrawing approval of the suspension plan shall not be earlier than 120 days following issuance of a final finding under paragraph (b)(6)(i) of this section.

(4) Within 30 days following a final finding under paragraph (b)(6)(i) of this section, the State must submit a transition plan to HHS.

■ 125. Section 600.145 is amended by revising paragraphs (a) and (f)(2) to read as follows:

§ 600.145 State program administration and operation.

(a) *Program operation.* The State must implement its BHP in accordance with:

(1) The approved and fully certified State BHP Blueprint, any approved modifications to the State BHP Blueprint and the requirements of this chapter and applicable law; or

(2) The approved suspension application described in § 600.140.

* * * * *

(f) * * *

(2) Eligibility and health services appeals as specified in 600.335.

* * * * *

■ 126. Section 600.170 amended by revising paragraph (a) to read as follows:

§ 600.170 Annual report content and timing.

(a) *Content.* (1) The State that is operating a BHP must submit an annual report that includes any evidence of fraud, waste, or abuse on the part of participating providers, plans, or the State BHP agency known to the State, and a detailed data-driven review of compliance with the following:

(i) Eligibility verification requirements for program participation as specified in § 600.345.

(ii) Limitations on the use of Federal funds received by the BHP as specified in § 600.705.

(iii) Requirements to collect quality and performance measures from all participating standard health plans focusing on quality of care and improved health outcomes as specified in sections 1311(c)(3) and (4) of the Affordable Care Act and as further described in § 600.415.

(iv) Requirements specified by the Secretary at least 120 days prior to the date of the annual report as requiring further study to assess continued State compliance with Federal law, regulations and the terms of the State's certified Blueprint, based on a Federal review of the BHP pursuant to § 600.200, and/or a list of any outstanding recommendations from any audit or evaluation conducted by the HHS Office of Inspector General that have not been fully implemented, including a statement describing the status of implementation and why implementation is not complete.

(2) A State that has suspended its BHP under § 600.140(b) of this part must submit an annual report that includes the following:

(i) The balance of the BHP trust fund and any interest accrued on that balance;

(ii) An assurance that the coverage provided to individuals who would be eligible for a BHP under § 600.305 of this part continues to meet the standards described in § 600.140(b)(1)(i), (ii), and (iii) of this part; and

(iii) Any additional information specified by the Secretary at least 120 days prior to the date of the annual report.

* * * * *

■ 127. Section 600.330 is amended by adding paragraph (f) to read as follows:

§ 600.330 Coordination with other insurance affordability programs.

* * * * *

(f) *Accessibility.* Eligibility notices must be written in plain language and be provided in a manner which ensures individuals with disabilities are provided with effective communication and takes steps to provide meaningful access to eligible individuals with limited English proficiency.

■ 128. Section 600.335 is amended by revising paragraph (b) to read as follows:

§ 600.335 Appeals.

* * * * *

(b) *Appeals process.* Individuals must be given the opportunity to appeal through the appeals rules of the State's Medicaid program:

(1) BHP eligibility determinations; and

(2) Delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of service.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

The following appendices will not appear in the Code of Federal Regulations.

APPENDIX 1: MIPS QUALITY MEASURES

Except as otherwise noted in this proposed rule, previously finalized measures and specialty measures sets will continue to apply for the CY 2024 performance period/2026 MIPS payment year and future years. Previously finalized measures and specialty measures sets are located in the CY 2017 through CY 2023 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, and 87 FR 70250 through 70633. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a consensus-based entity (CBE) are shown in Table A of this Appendix as follows: CBE # / eCQM CBE #.

Table Group A: New Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

A.1. Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)

Category	Description
CBE # / eCQM CBE #:	CBE 3633e (clinician level) CBE 3662e (clinician group level)
Quality #:	TBD
Description:	This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.
Measure Steward:	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)
Numerator:	Calculated CT size-adjusted dose greater than or equal to a threshold specific to the CT dose and Image Quality Category, or Calculated CT Global Noise value greater than or equal to a threshold specific to the CT Dose and Image Quality Category.
Denominator:	All CT scans in adults aged 18 years and older at the start of the measurement period that have a CT Dose and Image Quality Category and were performed during the measurement period.
Exclusions:	Denominator, where a CT scan with a CT Dose and Image Quality Category = full body.
Measure Type:	Intermediate Outcome
High Priority Measure:	Yes
Collection Type:	eCQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure to enhance patient safety and drive quality care in diagnostic radiology and assess outcomes of care for patients undergoing diagnostic CT imaging. This measure would improve patient safety by supporting clinician actions that are associated with a reduction in population-level cancer risks, in addition to associated cancer-related morbidity and mortality. As a result, this measure may also reduce the cost of caring for these patients. In the U.S., over 80 million CT scans are performed annually, and the radiation doses associated with these exams are a safety issue, as unnecessarily high radiation doses lead to harm by exposing patients to elevated cancer risk.[397] Numerous consensus-based clinical recommendations and guidelines ask radiologists to track, optimize, and lower the radiation doses they use for CT. These recommendations and guidelines are based on evidence that radiation doses are highly variable across institutions, higher than needed for diagnosis, and can lead to excessive patient harm. These recommendations and guidelines also indicate that physicians collect and compare their doses to benchmarks and reduce their doses if they are found to routinely exceed these

[397] Harvard Health Publishing (2021). Radiation Risk from Medical Imaging. *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

	benchmarks.[398] [399] This measure would support radiologists with a clinically relevant outcome measure within MIPS and meet the high priority definition for MIPS reporting as an outcome and patient safety measure. This measure received support for rulemaking from the Measure Applications Partnership (MAP) and was endorsed by a CBE (CBE 3633e/3662e). This measure would enhance the accessibility of data contained in electronic clinical data systems for increased efficiency, which could decrease clinician burden. Using electronic and standardized data already collected as part of routine clinical care, this measure assesses the radiation dose for every exam with complete information and assessment of imaging quality to ensure that efforts to reduce radiation dose do not result in poor image quality. It is also consistent with our emphasis on expanding the use of digital quality measures. The measure steward has created "as low as reasonably achievable" (ALARA) translation software that ingests radiology variables from Picture Archiving and Communication System (PACS), Radiology Information System (RIS), and electronic health records (EHR) systems for use with this quality measure. The software translates data from these systems into new variables that are specified in Logical Observation Identifiers Names and Codes (LOINC®), reflecting radiation dose and image quality information for each scan, that can then be used for reporting this measure. This translation software would be available to all clinicians and sites without cost, including any updates that need to be completed. Additionally, software tutorials, training, and webinars would also be provided at no cost. This measure is more robust than existing measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques, which is proposed for removal under Table C.12 of this Appendix to reduce duplication concurrent to the proposed adoption of this measure. This proposed measure assesses actual radiation dosing in patients undergoing diagnostic CT imaging, whereas the current measure assesses only utilization of dose optimization techniques (that is, a radiologist's choice of protocol) as documented within the final report. This proposed measure is an intermediate outcome measure of radiation dose, which is strongly associated with cancer risk. This measure covers the two key process of care components that determine the radiation doses: a) the choice of imaging protocol; and b) decisions regarding the technical settings used for that type of CT exam. It assesses radiation dose according to thresholds determined by the underlying clinical indication for imaging and not based upon radiologists' choice of protocol. In addition, this measure includes assessment of image quality as a means of thereby protecting the diagnostic value of CT imaging from unintended consequences of excessive dose reduction. Minimizing dose by adherence to these factors would reduce the number of future cancers that would result from the radiation exposure, and that could in turn lead to a reduction in morbidity, mortality, and health care costs.[400] [401] [402] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[398] Kanal, K. M., Butler, P. F., Sengupta, D., Bhargavan-Chatfield, M., Coombs, L. P., & Morin, R. L. (2017). US Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology, 284(1), 120-133. *https://pubs.rsna.org/doi/full/10.1148/radiol.2017161911.*

[399] American College of Radiology, The American Association of Physicists in Medicine, & The Society for Pediatric Radiology. (2022). ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment. *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CT-Equip.pdf, https://www.aapm.org/pubs/ACRAAPMCollaboration.asp.*

[400] Smith-Bindman, R., Wang, Y., Chu, P., Chung, R., Einstein, A. J., Balcombe, J., Cocker, M., Das, M., Delman, B. N., Flynn, M., Gould, R., Lee, R. K., Nelson, T. R., Schindera, S., Seibert, A., Starkey, J., Suntharalingam, S., Wetter, A., Wildberger, J. E., & Miglioretti, D. L. (2019). International Variation in Radiation Dose for Computed Tomography Examinations: Prospective Cohort Study. BMJ (Clinical research ed.), 364, k4931. *https://doi.org/10.1136/bmj.k4931.*

[401] Smith-Bindman, R., Chu, P., Wang, Y., Chung, R., Lopez-Solano, N., Einstein, A. J., Solberg, L., Cervantes, L. F., Yellen-Nelson, T., Boswell, W., Delman, B. N., Duong, P. A., Goode, A. R., Kasraie, N., Lee, R. K., Neill, R., Pahwa, A., Pike, P., Roehm, J., Schindera, S., … Miglioretti, D. L. (2020). Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. *JAMA Internal Medicine*, *180*(5), 666–675. *https://doi.org/10.1001/jamainternmed.2020.0064.*

[402] Berrington de González, A., Mahesh, M., Kim, K. P., Bhargavan, M., Lewis, R., Mettler, F., & Land, C. (2009). Projected Cancer Risks from Computed Tomographic Scans Performed in the United States in 2007. *Archives of Internal Medicine*, *169*(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

A.2. Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.
Measure Steward:	American Academy of Hospice and Palliative Medicine (AAHPM)
Numerator:	The Feeling Heard and Understood (HU) survey is calculated using top-box scoring within 2 months (60 days) of the ambulatory palliative care visit. Numerator 1: Patient felt heard and understood by this provider and team. Numerator 2: Patient felt this provider and team put my best interests first when making recommendations about my care. Numerator 3: Patient felt this provider and team saw me as a person, not just someone with a medical problem. Numerator 4: Patient felt this provider and team understood what is important to me in my life.
Denominator:	Denominator 1, 2, 3, and 4: All patients aged 18 years and older who had an ambulatory palliative care visit.
Exclusions:	Patients who did not complete at least one of the four patient experience HU survey items and return the HU survey within 60 days of the ambulatory palliative care visit. Patients who respond on the patient experience HU survey that they did not receive care by the listed ambulatory palliative care provider in the last 60 days (disavowal). Patients who were deceased when the HU survey reached them. Patients for whom a proxy completed the entire HU survey on their behalf for any reason (no patient involvement).
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this patient-reported outcome measure because it would fill a gap in the current quality measure inventory for patients receiving palliative care. The Feeling Heard and Understood survey was developed to capture patients' assessment of their care for ongoing quality reporting and improvement. This survey measures patients' satisfaction of their ambulatory palliative care experience based on how well they felt heard and understood by physicians, nurses, and other hospital staff. This proposed measure captures the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Assessment of how well patients feel heard and understood complements and adds an important dimension to existing quality measures of care planning by including patient experience of care for this unique patient population.[403] This measure is intended to facilitate and improve effective patient-provider communication that better engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. The outcome of this measure is that the patient feels heard and understood by the ambulatory palliative care provider and team. Through the benefits of enhanced patient-provider communication, this measure would improve the quality of care received and outcomes for patients receiving palliative care. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure is predicated on existing guidelines including the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care and supported by a systematic review of current evidence for palliative care interventions.[404] Evidence from the systematic review supports advanced care planning. Studies have shown that quality palliative care and communication between patients and providers are associated with increased preference-concordant care.[8] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[403] Edelen, M. O., Rodriguez, A., Huang, W., Gramling, R., & Ahluwalia, S. C. (2022). A Novel Scale to Assess Palliative Care Patients' Experience of Feeling Heard and Understood. Journal of Pain and Symptom Management, 63(5), 689–697.e1. *https://doi.org/10.1016/j.jpainsymman.2022.01.002.*

[404] Ahluwalia, S. C., Chen, C., Raaen, L., Motala, A., Walling, A. M., Chamberlin, M., O'Hanlon, C., Larkin, J., Lorenz, K., Akinniranye, O., & Hempel, S. (2018). A Systematic Review in Support of the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care, Fourth Edition. J Pain Symptom Manage, 56(6), 831-870. *https://www.nationalcoalitionhpc.org/ncp/.*

A.3. Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.
Measure Steward:	University of California, Irvine
Numerator:	Patients who are assessed for CVD risk via California Maternal Quality Care Collaborative (CMQCC) standardized algorithm. A completed CVD risk assessment will determine the patient to be at low risk or high risk of CVD. Patients will be assessed at their initial encounter with their healthcare provider for pregnancy-related care [prenatal visit, L&D, postpartum visit] and may need to repeat assessments if new symptoms develop.
Denominator:	Patients who have an office visit for prenatal or postpartum care, regardless of gestational age or prior prenatal care at other sites, for any age (including pregnant and postpartum minors), within outpatient obstetric (OB) visit at the hospital or in affiliated clinics; and labor and delivery (L&D) including private providers contracting with the hospital for delivery.
Exclusions:	Patients who have another reason for visiting the clinic [not prenatal or postpartum care] and have a positive pregnancy test but have not established the clinic as OB provider (e.g., plan to terminate the pregnancy or seek prenatal services elsewhere). Prior history of known CVD.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would fill a high priority clinical gap area under the wellness and prevention domain for maternal health. This process measure would address screening and care for pregnant/postpartum patients by assessing for the completion of a standardized CVD risk assessment for this high-risk population. This measure would represent a new quality measure clinical concept for maternal health. CVD is the leading cause of maternal mortality in the U.S., accounting for over one-third of all pregnancy-related deaths.[405] Peripartum cardiomyopathy (PPCM) constitutes the largest group among CVD-related deaths. About 24 percent of all CVD pregnancy-related deaths (and 31 percent of cardiomyopathy deaths) were determined to be potentially preventable.[406] CVD also accounts for many folds higher maternal morbidity, a longer length of hospital stays, intensive care unit (ICU) admissions, and future pregnancy risks.[407] This measure would monitor follow-up to universal cardiovascular risk assessment in all pregnant patients at their first encounter with an obstetrics provider.[408] The measure facilitates clinicians to evaluate pregnant or postpartum patients presenting with symptoms such as shortness of breath, cough, or excessive fatigue in the context of risk factors, vital sign abnormalities, and abnormal physical examination findings.[409] Normal physiological changes in pregnancy lead to signs and symptoms that may be indistinguishable from those of CVD. The overlap of signs and symptoms of normal pregnancy with those of CVD further complicates timely diagnosis. Most women who died from CVD during pregnancy and/or the postpartum period were not suspected of having a cardiac diagnosis and symptoms were attributed to an alternate diagnosis. Roughly 84 percent of pregnant patients who died from CVD presented with symptoms concerning for cardiopulmonary disease. However, only 61.1 percent of these patients were referred to cardiologists, and, of those, only 7 percent were referred antenatally. Given the large proportion of pregnancy-related mortality attributed to cardiovascular disease, these data suggest that an implementation of universal screening may improve overall

[405] Creanga, A. A., Syverson, C., Seed, K., & Callaghan, W. M. (2017). Pregnancy-Related Mortality in the United States, 2011-2013. Obstetrics and Gynecology, 130(2), 366–373. https://doi.org/10.1097/AOG.0000000000002114.

[406] Hameed, A.B., Foster, E., Main, E.K., Khandelwal, A., & Lawton, E.S. (2017). Cardiovascular Disease Assessment in Pregnant and Postpartum Women - California Maternal Quality Care Collaborative. Cardiovascular Disease in Pregnancy Toolkit. *https://www.cmqcc.org/content/cardiovascular-disease-assessment-pregnant-and-postpartum-women.*

[407] Fraser, A., Nelson, S. M., Macdonald-Wallis, C., Cherry, L., Butler, E., Sattar, N., & Lawlor, D. A. (2012). Associations of Pregnancy Complications with Calculated Cardiovascular Disease Risk and Cardiovascular Risk Factors in Middle Age: The Avon Longitudinal Study of Parents and Children. Circulation, 125(11), 1367–1380. *https://doi.org/10.1161/CirculationAHA.111.044784.*

[408] Writing Committee Members, Greenland, P., Alpert, J. S., Beller, G. A., Benjamin, E. J., Budoff, M. J., & Wenger, N. K. (2010). 2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 122(25), 2748-2764. *https://www.ahajournals.org/doi/10.1161/CIR.0b013e3182051bab.*

[409] Abbas, A. E., Lester, S. J., & Connolly, H. (2005). Pregnancy and the Cardiovascular System. International Journal of Cardiology, 98(2), 179-189. *https://www.internationaljournalofcardiology.com/article/S0167-5273(04)00040-3/fulltext.*

Category	Description
	maternal outcomes and lower overall healthcare costs.[410] Use of this measure promotes improvement in the screening of pregnant and postpartum women for the accurate diagnosis of heart failure or CVD versus attributing symptoms of pneumonia or other clinical side effects from pregnancy such as persistent cough, shortness of breath, and/or bilateral infiltrates on a chest x-ray. The intent of assessing the CVD risk during pregnancy/postpartum care is to increase education and awareness in this population and would empower patients to seek early medical care if new signs and symptoms develop that may be suggestive of CVD. It may have implications for long-term health outcomes with improvements in the CVD risk factor profile in the future. The use of a standardized CVD measure to risk-stratify pregnant and postpartum patients may improve the timely identification of CVD, thereby decreasing maternal morbidity and/or mortality. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The Alliance for Innovation on Maternal Health (AIM) identified the California Maternal Quality Care Collaborative (CMQCC) CVD Assessment Algorithm for Pregnant and Postpartum Patients as an emerging best practice and an important tool for assessing symptoms and risk in a standardized way and advocated for the use of the tool in its Cardiac Conditions in Obstetrical Care Bundle (CCOC).[411] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS *at https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[410] Chambers, M. E., De Zoysa, M. Y., & Hameed, A. B. (2022). Screening for Cardiovascular Disease in Pregnancy: Is There a Need? Journal of cardiovascular development and disease, 9(3), 89. *https://doi.org/10.3390/jcdd9030089.*

[411] Alliance for Innovation on Maternal Health. Cardiac Conditions in Obstetrical Care Bundle. *https://saferbirth.org/psbs/cardiac-conditions-in-obstetric-care/.*

A.4. First Year Standardized Waitlist Ratio (FYSWR)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75, and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The measure is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, adjusted for age, patient comorbidities, and other risk factors at incidence of dialysis.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Patients in the practitioner group's denominator listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year following initiation of dialysis.
Denominator:	The denominator for the First Year Standardized Waitlist Ratio (FYSWR) is the expected number of waitlist or living donor transplant events in the practitioner group according to each patient's treatment history for patients within the first year following initiation of dialysis, adjusted for age, incident comorbidities, dual Medicare-Medicaid eligibility, Area Deprivation Index (from patient's residence zip code) and transplant center characteristics, among patients under 75 years of age who were not already waitlisted and did not have kidney transplantation prior to the initiation of end-stage renal disease (ESRD) dialysis. The number of days at risk (time from start of dialysis to the earliest of being placed on the waitlist, receiving a living donor transplant, death, or one year from start of dialysis) for each patient is used to calculate the expected waitlist or living donor transplant events.
Exclusions:	Patients aged 75 or older on their initiation of dialysis date. Patients admitted to a skilled nursing facility (SNF). Patients in hospice on their initiation of dialysis date or during the month of evaluation. Patients that were on the kidney or kidney-pancreas waitlist prior to initiation of dialysis. Patients who had a transplant prior to initiation of dialysis.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.
Rationale:	We are proposing this measure because it addresses a CMS high priority clinical topic: patients with ESRD. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures (*https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease*). While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant (*https://pubmed.ncbi.nlm.nih.gov/34783494/*). This measure assesses whether patients that are in their first year of dialysis were placed on the kidney or kidney-pancreas transplant waitlist or received a living donor kidney transplant. Data submitted by the measure developer indicates a performance gap for a process that can be directly linked to improved patient outcomes. This measure is separate from the other transplant waitlist measure, proposed under Table A.5 of this Appendix, as it is limited to assessing the first year after initiation of dialysis and the timely addition of those patients to the transplant waitlist—a crucial step in driving positive outcomes in the patient population. National and large regional studies provide strong empirical support for the association between processes within the clinical scope and control of dialysis practitioners and subsequent patient transplant wait listing. For example, the clinical assessments, provisions and/or referrals made by a dialysis practitioner are contributing factors for consideration in patient transplant wait listing. In one large regional study conducted on facilities in the state of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics, and comorbidities.[412] There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$).[16] A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation (based on reporting on the Medical Evidence Form 2728 *(https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2728.pdf*) and subsequent access to kidney transplantation (wait listing or receipt of a live donor transplant).[413] Approximately 30 percent of patients were uninformed about kidney transplantation, and this was associated with half the rate of access to transplantation compared to patients who were informed.[17] In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients.[414] The provision of such information was associated with a near threefold increase in likelihood of wait listing.[18] The intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the intended objective of improving the overall

[412] Paul, S., Plantinga, L. C., Pastan, S. O., Gander, J. C., Mohan, S., & Patzer, R. E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. Clinical Journal of the American Society of Nephrology, 13(2), 282-289. *https://doi.org/10.2215/CJN.04690417.*

[413] Kucirka, L. M., Grams, M. E., Balhara, K. S., Jaar, B. G., & Segev, D. L. (2012). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. American Journal of Transplantation, 12(2), 351-357. *https://doi.org/10.1111/j.1600-6143.2011.03865.x.*

[414] Salter, M. L., Orandi, B., McAdams-DeMarco, M. A., Law, A., Meoni, L. A., Jaar, B. G., ... & Segev, D. L. (2014). Patient-and Provider-Reported Information about Transplantation and Subsequent Waitlisting. Journal of the American Society of Nephrology, 25(12), 2871-2877. *https://doi.org/10.1681/ASN.2013121298.*

Category	Description
	health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities and may include education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis practitioner groups. Aspects that are not directly in the clinician/groups control can be influenced through coordination of care, strong communication with transplant centers, and advocacy for patients. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The MAP did not support this measure for rulemaking with the potential for mitigation. The Renal Standing Committee raised concerns regarding the evidence base and specifications and recommended that this measure be resubmitted for endorsement by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies suggest a significant association between the clinician activities described above and the addition of patients to a transplant waitlist, which is necessary for patients to receive the improved outcomes associated with kidney transplant. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.5. Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Results are averaged across patients prevalent on the last day of each month during the reporting year. The measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Percentage of Prevalent Patients Waitlisted (PPPW): The adjusted count of patient months in which the patient at the dialysis practitioner or practitioner group practice is on any kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year. Numerator 2: Percentage of Prevalent Patients Waitlisted in Active (aPPPW): The adjusted count of patient months in which the patient at the dialysis practitioner or practitioner group practice is on any kidney or kidney-pancreas transplant waitlist in an active status as of the last day of each month during the reporting year.
Denominator:	Denominator 1 and 2: All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner or practitioner group practice according to each patient's treatment history on the last day of each reporting month during the performance year. If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.
Exclusions:	Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month. Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to the CMS-2728 form. Patients determined to be in hospice were excluded from month of evaluation and the remainder of reporting period. Patients with dementia at any time prior to or during the month.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.
Rationale:	We are proposing this measure because it addresses a CMS priority clinical topic: patients with ESRD. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures *(https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease)*. While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant *(https://pubmed.ncbi.nlm.nih.gov/34783494/)*. This measure captures the adjusted count of patient months on the kidney and kidney-pancreas transplant waitlist for all dialysis patients in a dialysis practitioner or group practice by assessing patient status on the last day of each month during the reporting year and those on the transplant waitlist in active status as of the last day of the month during the reporting year. This process measure is directly linked to driving positive outcomes and measure data indicates a performance gap. Most ESRD patients have to wait to eventually access a deceased donor transplant (national median of roughly 4 years).[415] Maintenance of 'active status' on the transplant list requires ongoing collaboration between dialysis practitioners, transplant centers, and transplant networks, thereby ensuring sustained suitability for a transplant while optimizing the health of patients.[20] This maintenance process is associated with higher transplantation rates and lowered mortality rates while on the waitlist.[416] In addition, the maintenance of 'active status' is an important health equity issue. Research has found disparities in access to kidney transplant by race.[417] Race-neutral efforts by clinicians to encourage maintenance of patients on the waitlist may reduce such disparities while improving their performance on this measure.[21] This measure assesses monthly wait listing in active status of patients. It also evaluates and encourages maintenance of patients on the waitlist. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. In contrast to this measure, the First Year Standardized Waitlist Ratio measure proposed under Table A.4 of this Appendix focuses solely on new wait listings and living donor kidney transplants to incentivize early action, rather than ongoing maintenance on the waitlist, which this measure assesses. The MAP conditionally supported this measure for rulemaking pending an update of the measure's specifications to include only the PPPW (CBE 3695) rate that was recommended for endorsement by the CBE's Renal Standing Committee. While we agree with the MAP that full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets

[415] Johansen, K. L., Chertow, G. M., Foley, R. N., Gilbertson, D. T., Herzog, C. A., Ishani, A., ... & Wetmore, J. B. (2021). US Renal Data System 2020 Annual Data Report: Epidemiology of Kidney Disease in the United States. American Journal of Kidney Diseases, 77(4), A7-A8. *https://www.ajkd.org/article/S0272-6386(21)00024-X/fulltext.*

[416] Grams, M. E., Massie, A. B., Schold, J. D., Chen, B. P., & Segev, D. L. (2013). Trends in the Inactive Kidney Transplant Waitlist and Implications for Candidate Survival. American Journal of Transplantation, 13(4), 1012-1018. *https://onlinelibrary.wiley.com/doi/pdf/10.1111/ajt.12143.*

[417] Kulkarni, S., Ladin, K., Haakinson, D., Greene, E., Li, L., & Deng, Y. (2019). Association of Racial Disparities with Access to Kidney Transplant after the Implementation of the New Kidney Allocation System. JAMA surgery, 154(7), 618-625. *https://jamanetwork.com/journals/jamasurgery/fullarticle/2729436.*

Category	Description
	the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The CBE recommended endorsement for the PPPW subset of this measure. It is important to include the aPPPW rate in this measure as well to capture patients in active waitlist status and the full scope of the transplant list and the movement of patients between active and inactive status. The studies cited above provide the evidentiary basis for the adoption of this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.6. Preventive Care and Wellness (composite)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization. Numerator 2: Patients who were administered any pneumococcal conjugate vaccine or polysaccharide vaccine on or after their 19th birthday and before the end of the measurement period. Numerator 3: Women with one or more mammograms any time on or between October 1 two years prior to the measurement period and the end of the measurement period. Numerator 4: Patients with one or more screenings for colorectal cancer. Appropriate screenings are defined by any one of the following criteria: - Fecal occult blood test (FOBT) during the measurement period. – Flexible sigmoidoscopy during the measurement period or the four years prior to the measurement period. – Colonoscopy during the measurement period or the nine years prior to the measurement period. – Computed tomography (CT) colonography during the measurement period or the four years prior to the measurement period. – Stool DNA (sDNA) with Fecal immunochemical test (FIT) during the measurement period or the two years prior to the measurement period. Numerator 5: Patients with a documented BMI during the encounter or during the previous twelve months, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the encounter. Numerator 6: - Patients who were screened for tobacco use at least once within the measurement period. – Patients who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period. – Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user. Numerator 7: Patient visits where patients were screened for high blood pressure AND have a recommended follow-up plan documented, as indicated, if the blood pressure is elevated or hypertensive.
Denominator:	Denominator 1: All patients aged 6 months and older seen for a visit during the measurement period. Denominator 2: Patients 65 years of age and older with a visit during the measurement period. Denominator 3: Women 41 – 74 years of age with a visit during the measurement period. Denominator 4: Patients 45-75 years of age with a visit during the measurement period. Denominator 5: All patients aged 18 and older on the date of the encounter with at least one qualifying encounter during the measurement period. Denominator 6: - All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. – All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period who were screened for tobacco use during the measurement period and identified as a tobacco user. – All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. Denominator 7: All patient visits for patients aged 18 years and older at the beginning of the measurement period.
Exclusions:	Denominator Exclusion Population 1: Hospice services provided to patient any time during the measurement period. Anaphylaxis due to the vaccine on or before the date of the encounter. Denominator Exclusion Population 2: Patient received hospice services any time during the measurement period. Patient had anaphylaxis due to the pneumococcal vaccine any time during or before the measurement period. Denominator Exclusion Population 3: - Women who had a bilateral mastectomy or who have a history of a bilateral mastectomy or for whom there is evidence of a right and a left unilateral mastectomy. Hospice services used by patient any time during the measurement period. – Palliative care services used by patient any time during the measurement period. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long term care with POS code 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. Denominator Exclusion Population 4: - Patients with a diagnosis or past history of total colectomy or colorectal cancer. – Patient was provided hospice services any time during the measurement period. – Patient was provided palliative care services any time during the measurement period. Patient age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. – Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. Denominator Exclusion Population 5: - Documentation stating the patient has received or is currently receiving palliative or hospice care. – Documentation of patient pregnancy anytime during the measurement period prior to and including the current encounter. Denominator Exclusion Population 6: Hospice services provided to patient any time during the measurement period (applicable to each of the 3 performance rates). Denominator Exclusion Population 7: Patient not eligible due to active diagnosis of hypertension.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications

Category	Description
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
	We are proposing this composite measure which combines seven current preventive care measures with age and sex appropriate preventive screenings and wellness services to create a robust, broadly encompassing preventive care assessment. The measure developer submitted data demonstrating a performance gap for the composite measure. In testing, the developer identified a performance gap, where median performance on the combined measure was 52.7 percent, with a standard deviation of 11.2 percent. Initially, this measure would be implemented as a weighted average analytic, representing performance for quality actions linked to positive patient outcomes. This measure would set a more stringent performance standard by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care while ensuring more all-inclusive preventive care. By setting a more stringent performance standard through use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, we gain a better picture of overall preventive care practices as each component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/*). This allows for early diagnosis of disease, thereby leading to earlier treatment, improved health outcomes, and a reduction in healthcare associated costs (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265933/.*
Rationale:	This measure consists of seven preventive care and screening processes that are consistent with guidelines from the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the American Association of Clinical Endocrinology (AACE), and the American College of Endocrinology (ACE). The seven screening processes are influenza immunization, pneumococcal immunization, breast and colorectal cancer screening, body mass index screening, tobacco use screening and cessation intervention, and screening for high blood pressure with follow-up. Each process received a recommendation of at least "Strong" or an equivalent rating from the corresponding body identified above.[418] The basis for each constituent measure was previously described in our prior rulemaking under the 2013 Physician Quality Reporting System (PQRS) in the CY 2012 PFS final rule (77 FR 69215 through 69267: Table 95 and 77 FR 69269 through 69271: Table 96), and each measure was retained with the implementation of MIPS (81 FR 77558 through 77675). In connection with the proposal of this measure, we also propose to remove measures Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan from traditional MIPS, while retaining those three measures for use in relevant MVPs as discussed under Table Group CC of this Appendix. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the

[418] Component 1: Grohskopf, L. A., Alyanak, E., Ferdinands, J. M., Broder, K. R., Blanton, L. H., Talbot, H. K., & Fry, A. M. (2021). Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recommendations and Reports, 70(5), 1. *http://dx.doi.org/10.15585/mmwr.rr7005a1.*
Component 2: Kobayashi, M., Farrar, J. L., Gierke, R., Britton, A., Childs, L., Leidner, A. J., ... & Pilishvili, T. (2022). Use of 15-valent Pneumococcal Conjugate Vaccine and 20-valent Pneumococcal Conjugate Vaccine Among US Adults: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2022. Morbidity and Mortality Weekly Report, 71(4), 109-117. *https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7104a1-H.pdf.*
Component 3: Siu, A. L., & US Preventive Services Task Force. (2016). Screening for Breast Cancer: US Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine, 164(4), 279-296. *https://www.acpjournals.org/doi/10.7326/M15-2886.*
Component 4: Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., ... & US Preventive Services Task Force. (2021). Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA, 325(19), 1965-1977. *https://doi.org/10.1001/jama.2021.6238.*
Component 5: Garvey, W. T., Mechanick, J. I., Brett, E. M., Garber, A. J., Hurley, D. L., Jastreboff, A. M., Nadolsky, K., Pessah-Pollack, R., Plodkowski, R., & Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines (2016). American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocrine Practice: Official Journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists, 22 Suppl 3, 1–203. *https://doi.org/10.4158/EP161365.GL.*
Component 6: Krist, A. H., Davidson, K. W., Mangione, C. M., Barry, M. J., Cabana, M., Caughey, A. B., ... & US Preventive Services Task Force. (2021). Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement. JAMA, 325(3), 265-279. *https://doi.org/10.1001/jama.2020.25019.*
Component 7: Krist, A. H., Davidson, K. W., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., ... & US Preventive Services Task Force. (2021). Screening for Hypertension in Adults: US Preventive Services Task Force Reaffirmation Recommendation Statement. JAMA, 325(16), 1650-1656. *https://doi.org/10.1001/jama.2021.4987.*

Category	Description
	statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The preventive care and wellness composite measure is supported based upon the evidence discussed and cited within the respective rules in which each constituent measure was proposed and finalized as indicated previously in the rationale. A study of preventive services covered under the Affordable Care Act examined the extent to which lives could be saved if adults over 18 received them, including some addressed by this measure. The authors found preventive services ameliorate 9 of the 10 leading causes of death in America and could save at least 100,000 lives,[419] providing support for this composite measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[419] Fox, J.B., & F.E. Shaw. (2015). Clinical Preventive Services Coverage and the Affordable Care Act. American Journal of Public Health, 105(1), e7-e10.

A.7. Connection to Community Service Provider

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.
Measure Steward:	Oregon Community Health Information Network (OCHIN)
Numerator:	Patients who had contact with a CSP for at least one of their HRSNs within 60 days after screening.
Denominator:	Patients aged 18 or older who screened positive for at least 1 of the 5 HRSNs domains (food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety) during the measurement period.
Exclusions:	Patients who are counseled on connection with a CSP and explicitly opt-out.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would address five social and economic determinants we have identified as both a measurement priority and performance gap. Addressing this gap is a central part of our Health Equity strategic plan pillar, as discussed in the 2023 PFS final rule (87 FR 70253 through 70259) for previously finalized measure Q487: Screening for Social Drivers of Health. This proposed measure assesses patients who screen positive for one or more of the five HRSNs for contact with a CSP for at least one of their HRSNs within 60 days of the screening. The five HRSNs are food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety. A CSP is defined as any independent, for-profit, non-profit, state, territorial, or local agency capable of addressing core or supplemental HRSNs. This measure excludes patients who opt out of contact with a CSP. Studies have shown that social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health (*https://doi.org/10.7326/M17-2441*). Thus, systematically screening patients for social drivers of health and referring them to community-based resources as needed can result in improved health outcomes (*https://doi.org/10.7326/M17-2441*). Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, improve a patient's overall health and well-being (*https://doi.org/10.31478/201705b*). As an example, early findings from the CMMI Accountable Health Communities (AHC) Model shows those patients within the "Assistance Track" (the intervention group offering navigation assistance to connect patients with the community services they need) had 9 percent fewer emergency department visits as compared to their control group counterparts who did not receive navigation assistance during the first year following screening (*https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*). The USPSTF also recently released a technical brief on screening and interventions for social risk factors, which notes that social risk factors are mentioned in two-thirds of USPSTF recommendation statements, and six other professional medical organizations explicitly promote clinician engagement in social risk screening and referrals.[420] The report highlights that, in studies reporting these outcomes, there were few if any unintended consequences resulting from the implementation of social risk screening and intervention despite perceived barriers to implementation.[24] This measure leverages the data and experience from the AHC Model (*https://innovation.cms.gov/innovation-models/ahcm*), which has screened nearly one million beneficiaries for HRSNs. The AHC Model requires that all AHC-screened beneficiaries with unmet HRSNs receive community referral summaries tailored to their needs (*https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*). This measure is consistent with our priority to advance health equity throughout our various programs. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive (*https://www.cms.gov/pillar/health-equity*). The MAP conditionally supported this measure for rulemaking pending testing indicating the measure is reliable, valid, and feasible, and endorsement by a CBE. While we agree with the MAP that the full CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies show that social drivers of health contribute to poorer health. Referrals to CSPs provide a direct means through which clinicians can assist patients in overcoming social drivers of health. As we have previously stated, we request that interested parties consider when submitting a quality measure for possible inclusion whether the measure is "beyond the measure concept phase of development and [has] started testing, at a minimum, with strong encouragement and preference for measures that have completed or are near completion of reliability and validity testing" (83 FR 53636; 84 FR 62954). While we consider whether or not a measure is fully tested, it is not the only relevant

[420] Eder, M., Henninger, M., Durbin, S., Iacocca, M. O., Martin, A., Gottlieb, L. M., & Lin, J. S. (2021). Screening and Interventions for Social Risk Factors: Technical Brief to Support the US Preventive Services Task Force. JAMA, 326(14), 1416–1428. *https://doi.org/10.1001/jama.2021.12825.*

Category	Description
	standard. This measure builds upon measure Q487, collecting data on positive screening and subsequent connection to a CSP for assistance. Having both measures in MIPS allows for assessment of two critical steps in addressing health equity; first ensuring that screening is completed on all patients and the second connecting patients who are facing a HRSN with resources that can help address these needs. Addressing health equity is a pressing issue which deserves serious focus and rapid action. This measure is an important next step for use of drivers of health (DOH) data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Clinicians choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. This is vital to allow further testing and development of additional health equity outcome measures. While we would encourage submission of health equity related measures, MIPS does allow for clinician choice in quality measure selection and would not require submission of this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.8. Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.
Measure Steward:	American Society of Retina Specialists
Numerator:	Number of patients who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye listed in chart OR if the IOP was >25 mm Hg, a plan of care was documented.
Denominator:	Patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) with a patient encounter during the performance period.
Exclusions:	Patients with a diagnosis of hypotony.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this process measure because it would address the MIPS priority area of patient safety. Patients treated with corticosteroid therapy are at increased risk for elevated IOP leading to steroid-induced glaucoma and their quality of life may be negatively impacted due to visual impairments.[421] Ensuring that appropriate monitoring is conducted to detect and treat this complication is important to prevent significant visual morbidity. Researchers who completed a systemic review identified that 10.9 percent to 79.0 percent of patients will develop clinically significant IOP elevations and should have a follow-up within 7 weeks, based upon randomized controlled trials.[422] This measure would directly measure IOP after corticosteroid injections. The intent of this measure encourages clinicians to screen and treat patients identified with an elevated IOP in a timely manner. Currently there are no measures in MIPS that address the screening and plan of care for elevated IOP following intravitreal or periocular steroid therapy. This measure would also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Current clinical guidelines do not address the need to assess for elevated IOP following corticosteroid injection; however, data has demonstrated that patients treated with corticosteroid therapy are at increased risk for elevated IOP leading to steroid induced glaucoma, visual impairment, and overall poor quality of life.[423] [424] Several randomized clinical trials and a systematic review identified that IOPs typically peak around 7 to 9 weeks.[26] [425] [426] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[421] American Academy of Ophthalmology. (2022, March 29). Steroid-Induced Glaucoma. EyeWiki. *https://eyewiki.aao.org/Steroid-Induced_Glaucoma.*

[422] Kiddee, W., Trope, G. E., Sheng, L., Beltran-Agullo, L., Smith, M., Strungaru, M. H., ... & Buys, Y. M. (2013). Intraocular Pressure Monitoring Post Intravitreal Steroids: A Systematic Review. Survey of Ophthalmology, 58(4), 291-310. *https://doi.org/10.1016/j.survophthal.2012.08.003.*

[423] Breusegem, C., Vandewalle, E., Van Calster, J., Stalmans, I., & Zeyen, T. (2009). Predictive Value of a Topical Dexamethasone Provocative Test Before Intravitreal Triamcinolone Acetonide Injection. Investigative Ophthalmology & Visual Science, 50(2), 573–576. *https://doi.org/10.1167/iovs.08-2625.*

[424] Haller, J. A., Bandello, F., Belfort, R., Jr, Blumenkranz, M. S., Gillies, M., Heier, J., Loewenstein, A., Yoon, Y. H., Jiao, J., Li, X. Y., Whitcup, S. M., Ozurdex GENEVA Study Group, & Li, J. (2011). Dexamethasone Intravitreal Implant in Patients with Macular Edema Related to Branch or Central Retinal Vein Occlusion Twelve-Month Study Results. Ophthalmology, 118(12), 2453–2460. *https://doi.org/10.1016/j.ophtha.2011.05.014.*

[425] Haller, J. A., Bandello, F., Belfort, R., Jr, Blumenkranz, M. S., Gillies, M., Heier, J., Loewenstein, A., Yoon, Y. H., Jacques, M. L., Jiao, J., Li, X. Y., Whitcup, S. M., & OZURDEX GENEVA Study Group (2010). Randomized, Sham-Controlled Trial of Dexamethasone Intravitreal Implant in Patients with Macular Edema due to Retinal Vein Occlusion. Ophthalmology, 117(6), 1134–1146.e3. *https://doi.org/10.1016/j.ophtha.2010.03.032.*

[426] Aref, A. A., Scott, I. U., Oden, N. L., Ip, M. S., Blodi, B. A., & Van Veldhuisen, P. C. (2015). Incidence, Risk Factors, and Timing of Elevated Intraocular Pressure After Intravitreal Triamcinolone Acetonide Injection for Macular Edema Secondary to Retinal Vein Occlusion SCORE Study Report 15. JAMA Ophthalmology, 133(9), 1022-1029. *https://doi.org/10.1001/jamaophthalmol.2015.1823.*

A.9. Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks
Measure Steward:	American Society of Retina Specialists
Numerator:	Patients who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Denominator:	Patients with a diagnosis of acute PVD in either eye and eligible encounter during measurement period.
Exclusions:	Patients with a post-operative encounter of the eye with the acute PVD within 2 weeks before the initial encounter or 8 weeks after initial acute PVD encounter. Patients with a diagnosis of acute vitreous hemorrhage.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this process measure because it addresses the appropriate screening and follow-up for patients with PVD. PVD puts patients at an increased risk of retinal tears.[427] PVD complicated by retinal tear may result in retinal detachment or epiretinal membrane, causing loss of vision.[31] When retinal tears are treated promptly, the risk of detachment decreases driving positive health outcomes. While the onset of PVD is generally not preventable, it is critical to identify and treat any associated retinal tears through a prompt and appropriate initial exam and re-evaluation.[32] Prompt identification of complications will allow for expedient treatment, minimizing the potential for further complications such as retinal detachment improving a patient's quality of life.[32] Currently there are no measures in MIPS that address care improvement for patients at risk of retinal tearing due to PVD. This measure is intended to assess compliance with the current guidelines published by the American Academy of Ophthalmology on PVD and retinal breaks, which calls for re-evaluation of patients within eight weeks of their diagnosis of PVD.[428] Such re-evaluations are associated with prompt identification of complications which will allow for expedient onset of treatment, minimizing the potential for further complications, such as retinal detachment improving a patient's quality of life.[32] This measure would also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE, with a specific review of the validity of the measure specifications and performance gap of the measure. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As stated above, PVD is not preventable; however, with prompt evaluations, and expedited treatment, these complications may be lessened, supporting the need for this measure. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[427] American Society of Retinal Specialists. (2016). Retina Health Series: Posterior Vitreous Detachment. Available at: *https://www.asrs.org/content/documents/fact_sheet_1_posterior_vitreous_detachment_new.pdf.*

[428] American Academy of Ophthalmology Retina/Vitreous Preferred Practice Pattern Panel. (2019). Preferred Practice Pattern® Guidelines. Posterior Vitreous Detachment, Retinal Breaks, and Lattice Degeneration PPP 2019. San Francisco, CA: American Academy of Ophthalmology. Available at *www.aao.org/ppp*.

A.10. Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks
Measure Steward:	American Society of Retina Specialists
Numerator:	Patients who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks
Denominator:	Patients with a diagnosis of acute PVD and acute vitreous hemorrhage in either eye and eligible encounter during performance period.
Exclusions:	Patients with a post-operative encounter of the eye with the acute PVD within 2 weeks before the initial encounter or 2 weeks after initial acute PVD encounter.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it addresses appropriate screening and follow-up for patients with PVD and acute vitreous hemorrhage, due to the increased risk for complications such as retinal tears and subsequent retinal detachment in this population. This measure would address the MIPS priority area of patient safety by incentivizing physicians to see patients in a timely manner. It was found that two-thirds of PVD patients presenting with associated vitreous hemorrhage, had at least one retinal break and therefore, require a more expedient follow-up evaluation. This measure would also provide a clinically relevant measure option for retinal specialists. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. When retinal tears are treated promptly, the risk of detachment decreases driving positive health outcomes. While the onset of PVD is generally not preventable, it is critical to identify and treat any associated retinal tears through a prompt and appropriate evaluation. Prompt identification of complications will allow for expedient onset of treatment, minimizing the potential for further complications such as retinal detachment improving a patient's quality of life. The current guideline published by the American Academy of Ophthalmology on posterior vitreous detachment (PVD) and retinal breaks supports this measure. The guideline states, "selected patients, particularly those with any degree of vitreous pigment, vitreous or retinal hemorrhage, or visible vitreoretinal traction, should be asked to return for a second examination promptly if they have new symptoms or within 6 weeks following the onset of PVD symptoms."[32] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

A.11. Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.
Measure Steward:	American Psychiatric Association
Numerator:	Patients who demonstrated improvement or maintenance of functioning, as demonstrated by results of follow-up assessment using the 12-item WHODAS 2.0 or Sheehan Disability Scale 30 to 180 days after the index assessment during the performance period.
Denominator:	Patients aged 18 and older with a mental and/or substance use disorder and an encounter with an index assessment completed using the 12-item WHODAS 2.0 or Sheehan Disability Scale (SDS) during the denominator identification period.
Exclusions:	Patient situations, at any point during the denominator identification period, where the patient's functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools, such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders, - Patients who died during the performance period.
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it would address a high priority specialty area and a high priority clinical topic, mental health and substance use disorders and is not duplicative of any existing measure within MIPS. The mental and substance use disorders captured by this measure are among the 25 leading causes of years lived with disabilities as well as contributing significantly to the global burden of disease.[429] Twenty-two percent of U.S. adults (57.8 million individuals aged 18 and older) have a mental illness diagnosis and 17.3 percent (44 million individuals aged 18 and older) have a substance use disorder diagnosis (*https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases#annual-national-report*). Individuals with mental disorders are more likely to report severe impairment in functioning when compared to patients with chronic medical conditions.[430] Improvement or maintaining functioning is strongly predictive of a positive outcome.[34] Patients afflicted with mental disorders show increased rates of morbidity from general medical conditions in addition to a higher risk of premature mortality.[34] Considering these factors and the contribution of mental health disorders to the global burden of disease, gaps persist in healthcare. This necessitates improvement in the overall quality of mental health care.[34 431] Outcome measures are critical to evaluating patient improvements based on current patient care, assisting clinicians in planning, monitoring, and adjusting care plans and treatment options.[432] This measure is comprehensive and broadly inclusive of mental health and substance use disorders. It uses a measurement-based care framework for implementation across various settings and populations to assess the outcome of care for patients with mental health and substance use disorders. The MAP conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. A measure focused on functioning is linked to a decrease in negative symptoms and a reduction in resources utilized, making it have the potential to reduce economic burden. Using a screening tool will allow clinicians to better assess patient functioning over time and adjustment treatment accordingly. Measurement-based care with the use of a valid and reliable tool provides valuable information about functioning.[35] Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[429] The U.S. Burden of Disease Collaborators. (2018). The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. Journal of the American Medical Association, 319(14), 1444–1472. *https://doi.org/10.1001/jama.2018.0158.*

[430] Druss, B. G., Hwang, I., Petukhova, M., Sampson, N. A., Wang, P. S., & Kessler, R. C. (2009). Impairment in Role Functioning in Mental and Chronic Medical Disorders in the United States: Results from the National Comorbidity Survey Replication. Molecular Psychiatry, 14(7), 728-737. *https://doi.org/10.1038/mp.2008.13.*

[431] Scott, K., & Lewis, C. C. (2015). Using Measurement-Based Care to Enhance Any Treatment. Cognitive and Behavioral Practice, 22(1), 49–59. *https://doi.org/10.1016/j.cbpra.2014.01.010.*

[432] Kilbourne, A. M., Beck, K., Spaeth-Rublee, B., Ramanuj, P., O'Brien, R. W., Tomoyasu, N., & Pincus, H. A. (2018). Measuring and Improving Quality of Mental Health Care: A Global Perspective. World Psychiatry, 17(1), 30-38. *https://doi.org/10.1002/wps.20482.*

A.12. Gains in Patient Activation Measure (PAM®) Scores at 12 Months

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The Patient Activation Measure® (PAM®) is a 10 or 13 item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.
Measure Steward:	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
Numerator:	Numerator 1: Patients with a Baseline PAM® score and then a second score taken within 12 months of the baseline (but not less than 6 months). Numerator 2: Percentage of eligible patients who achieved a net increase in PAM® score of at least 3 points in a 6 to 12 month period (passing). Numerator 3: Percentage of eligible patients who achieved a net increase in PAM® score of at least 6 points in a 6 to 12 month period (excellent). Numerator 4: The average change (net difference) for all eligible patients between the baseline PAM® score and the second score taken within 12 months of the baseline (but not less than 6 months).
Denominator:	Denominator 1: Patients aged 14 and older with a qualifying visit at least once during the performance period. Denominator 2, 3 and 4: Patients aged 14 years and older with Performance Met for Submission Criteria 1 who had a baseline PAM® score and a second score within 6 to 12 month of baseline PAM® score and who were seen for a qualifying visit at least once during the performance period.
Exclusions:	Denominator 1, 2, 3: Diagnosis of Dementia; Diagnosis of Huntington's disease; Diagnosis of Cognitive Impairment or Alzheimer's disease Denominator 4: None
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	1.Clinicians must have collected a follow-up PAM® survey on at least 50 percent of all eligible patients during the performance period 2.Clinicians must have administered a follow-up PAM® survey to a minimum of 40 unique patients
Rationale:	We are proposing this measure because this measure, while disease agnostic, addresses chronic conditions and patient reported outcomes, both of which are high priority areas for measure consideration for MIPS. This PRO-PM provides a standardized method for clinicians to assess patient activation through the continuum of care. The PAM® survey[433] collects information directly from patients regarding their knowledge, skill, and confidence in managing their health and healthcare. This measure has been used with a wide variety of chronic conditions, as well as with people with no medical diagnosis. The intent of the PAM® is to assess an individual's ability to manage their own health and health care. According to the measure developer, the PAM® is predictive of most health outcomes, including such diverse outcomes as how a patient fares after orthopedic surgery; remission of depression over time; the likelihood of hospital re-admission or ambulatory care sensitive (ACS) utilization; the trajectory of a chronic disease over time; and even the likelihood of a new chronic disease diagnosis in the coming year.[434] [435] [436] [437] The PAM® surveys the knowledge, skill, and confidence necessary for self-management on a 0-100 point scale that can be broken down into four levels from low activation to high activation. The 13 (or 10) item survey has strong measurement properties and is predictive of most health behaviors and many clinical outcomes.[438] PAM® scores are also predictive of health care costs, with lower scores predictive of higher costs.[37] The PAM® is in use both in the U.S. and internationally in research as well as clinical settings and has been translated into

[433] PAM Survey: *https://www.phreesia.com/patient-activation-measure/ ?utm_source=google&utm_ medium=paid_ search&utm_ destinationmedium=mql_form&utm_campaign=payer_care_management_paid_search&utm_vendor=phreesia&ut m_audience1=payer&utm_content=648172611574&utm_destinationco.*

[434] Greene, J., Hibbard, J. H., Sacks, R., Overton, V., & Parrotta, C. D. (2015). When Patient Activation Levels Change, Health Outcomes and Costs Change Too. Health Affairs, 34(3), 431-437. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0452.*

[435] Mitchell, S. E., Gardiner, P. M., Sadikova, E., Martin, J. M., Jack, B. W., Hibbard, J. H., & Paasche-Orlow, M. K. (2014). Patient Activation and 30-day Post-discharge Hospital Utilization. Journal of General Internal Medicine, 29(2), 349–355. *https://doi.org/10.1007/s11606-013-2647-2.*

[436] Sacks, R. M., Greene, J., Hibbard, J. H., & Overton, V. (2014). How Well Do Patient Activation Scores Predict Depression Outcomes One Year Later? Journal of Affective Disorders, 169, 1-6. *https://doi.org/10.1016/j.jad.2014.07.030.*

[437] Hibbard, J. H., Greene, J., Sacks, R. M., Overton, V., & Parrotta, C. (2017). Improving Population Health Management Strategies: Identifying Patients Who Are More Likely to Be Users of Avoidable Costly Care and Those More Likely to Develop a New Chronic Disease. Health Services Research, 52(4), 1297–1309. *https://doi.org/10.1111/1475-6773.12545.*

[438] Hibbard, J. H., Stockard, J., Mahoney, E. R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Services Research,

Category	Description
	more than 30 languages.[37] The measure developer has been able to validate the instrument with people of different racial and ethnic backgrounds, and with people from different socio-economic levels, owing to the widespread utilization of PAM® by researchers all over the world.[37 42] A version of this measure, as well as the PAM® survey, is used in a number of Federal quality and payment programs.[37] Additionally, it is currently a required assessment in the CMMI Kidney Care Choices (KCC) *(https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model*) and Maternal Opioid Misuse (*https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model*) alternative payment models. This measure received support for rulemaking from the MAP. The MAP discussed concerns regarding the potential proprietary nature of the assessment, costs to integrate the measure into EHRs, and the licensing for integration into EHRs. The measure developer clarified the measure would be available without licensing costs for implementation. MAP also raised concerns regarding the specificity of the denominator definition/population. However, this measure is currently implemented in other Federal quality and payment programs. The measure is also aligned with the CBE endorsed measure CBE 2483: Gains in Patient Activation (PAM®) Scores at 12 Months, which is applicable to the "Group/Practice" level of analysis. Overall, the MAP agreed this measure contributes to patient-centered care and supported the measure as a PRO-PM. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

A.13. Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
Measure Steward:	American Psychiatric Association
Numerator:	Numerator 1: Patients for whom a completed suicide safety plan is initiated, reviewed, or updated in collaboration between the patient and their clinician at the time the suicidal ideation behavior or risk is identified (concurrent or within 24 hours of index clinical encounter), during the measurement period. Numerator 2: Patients for whom a suicide safety plan is initiated, reviewed, or updated in collaboration between the individual and their clinician at the time the suicidal ideation, behavior or risk is identified (concurrent or within 24 hours of clinical encounter) AND reviewed and updated within 120 days after the index clinical encounter after initiation.
Denominator:	Denominator 1 and 2: Patients aged 18 and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms or suicide risk at a clinical encounter during the denominator identification period.
Exclusions:	Denominator 1 and 2: Patients whose functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders. Patients who died during the measurement period.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it focuses on a process where initiating and reviewing a suicide safety plan with a patient at risk of suicide is a proxy for the clinical outcome of a reduction in suicides, suicide attempts, and suicidal ideation; thereby, addressing behavioral health. Incorporating this measure into MIPS would encourage measure adoption, which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. This measure represents a high priority area for MIPS due to its focus on improved outcomes in mental health. The use of standardized patient-reported outcome measures (PROMs) associated with suicide ideation and behavior and clinician-rated assessments of suicide risk, including the use of safety plans, varies within and across behavioral health specialties as well as primary care and emergency care settings, where suicidal persons often present for care. Currently, only hard-copy versions of safety planning documents have been used in most settings, with slow uptake of electronic versions.[43] Hard-copy safety plans provided to patients are prone to misplacement, creating a barrier to their use and follow-up.[439] Even with use of suicide safety plans at an index visit, research has found that less than 50 percent of suicidal persons had explicit evidence of ongoing review or utilization of the safety plan in ongoing treatments.[440] The implementation of this proposed quality measure is intended to incentivize quality care that addresses the low rate of (re)assessment and poor outcomes. This quality measure would help to advance the Zero Suicide initiative set forth in the National Strategy for Suicide Prevention (*https://theactionalliance.org/our-strategy/national-strategy-suicide-prevention*) and ultimately improve the quality of care for patients with suicide ideation, behaviors, or suicide risk. There is one existing measure in MIPS that addresses suicide: measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. Though conceptually related, the proposed measure distinguishes itself from measure Q107 by focusing on a care process that is directly designed to mitigate suicide risk, as opposed to merely completely screening for it. There is an outcome measure in MIPS focused on a related mental health area: measure Q370: Depression Remission at Twelve Months. While PHQ-9, the assessment used in measure Q370[441], does include one question about self-harm, this measure is specific to depression. The proposed measure would include patients with other behavioral health conditions who are at risk of suicide and appropriate for assessment of the clinical quality action within the measure. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This suicide prevention measure could be clinically useful for clinicians treating individuals at increased risk for suicide as it is associated with reduction in suicidal behaviors and may improve quality of care for at risk patients.

[439] Little, V., Neufeld, J., & Cole, A. R. (2018). Integrating Safety Plans for Suicidal Patients into Patient Portals: Challenges and Opportunities. Psychiatric services (Washington, D.C.), 69(6), 618–619. *https://doi.org/10.1176/appi.ps.201700458*.

[440] Gamarra, J. M., Luciano, M. T., Gradus, J. L., & Wiltsey Stirman, S. (2015). Assessing Variability and Implementation Fidelity of Suicide Prevention Safety Planning in a Regional VA Healthcare System. Crisis, 36(6), 433–439. *https://doi.org/10.1027/0227-5910/a000345*.

[441] *See https://www.apa.org/depression-guideline/patient-health-questionnaire.pdf.*

Category	Description
	Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

A.14. Reduction in Suicidal Ideation or Behavior Symptoms

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.
Measure Steward:	American Psychiatric Association
Numerator:	Patients who demonstrated a reduction in suicidal ideation and/or behavior symptoms as demonstrated by results of a follow-up assessment using the C-SSRS within 120 days after the index assessment during the measurement period.
Denominator:	Patients aged 18 and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms OR deemed a suicide risk based on their clinician's evaluation at an encounter with an index assessment completed using the C-SSRS during the denominator identification period.
Exclusions:	Patients whose functional capacity or motivation (or lack thereof) to improve may impact the accuracy of results of validated tools such as delirium, dementia, intellectual disabilities, and pervasive and specific development disorders. Patients who died during the measurement period
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this PRO-PM because this measure focuses on mental health and substance use disorder (SUD), which are CMS high priority areas for MIPS measure consideration. This measure collects information related to a demonstrated reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' *(https://www.cms.gov/files/document/cssrs-screen-version-instrument.pdf)* versus 'Since Last Visit', taken within 120 days after an index assessment. Incorporating this measure into MIPS would encourage and support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. This measure would represent another valuable PRO-PM measure for interested parties to report within MIPS, representing the continuum of care and improved health outcomes for individuals with suicidal ideation, behavior, or risk. This clinical outcome measure assesses reductions in suicidal ideation that are likely associated with reductions in suicides and suicide attempts. Suicide is a preventable cause of lost lives, yet each year over 40,000 Americans die by suicide (*https://www.cdc.gov/nchs/products/databriefs/db330.htm*). Safety planning, means reduction, and connecting suicidal persons to treatment are effective and critical elements in suicide prevention (*https://theactionalliance.org/sites/default/files/action_alliance_recommended_standard_care_final.pdf*), as discussed in the most updated clinical practice guidelines for assessment and treatment of suicidal persons (*https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf*). This measure, which focuses on the reduction of suicidal ideation, conceptually addresses behavioral health, and is a high priority area for MIPS. There is one existing measure in MIPS that addresses suicide: measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. Though conceptually related, this measure distinguishes itself by focusing on the relevant clinical outcome. There is an outcome measure in MIPS focused on a related mental health area: measure Q370: Depression Remission at Twelve Months. The instrument used to assess remission in measure Q370, the PHQ-9, does include one question about self-harm; however, this measure is specific to depression. This proposed measure would include patients with other behavioral health conditions who are at risk of suicide and appropriate for assessment of the clinical quality action within the measure. This measure received conditional support for rulemaking from the MAP pending CBE endorsement. While we agree with the MAP that CBE endorsement is preferred, this measure should nonetheless be added to MIPS, and it meets the statutory standard for inclusion as a non-endorsed measure. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Table Group B: Modifications to Previously Finalized Specialty Measures Sets Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

We are proposing to modify the below previously finalized specialty measures sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D of this Appendix. In the first column, existing measures with substantive changes described in Table Group D of this Appendix are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

Under § 414.1305, a high priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure. Further details of these types of measures are located in the CMS Measures Management System Hub (*mmshub.cms.gov*).

It should be noted that for the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface as a collection type is only available for APM Entities, specifically Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type is not listed in any specialty set under Table Group B of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this proposed rule. For information regarding proposed changes to the CMS Web Interface measures available for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

Note: The following specialty sets have no addition tables, no removal tables, and no substantive changes proposed for the CY 2024 performance period/2026 MIPS payment year: Anesthesiology, Electrophysiology Cardiac Specialist, and Pathology.

Note: Previously finalized measures that have no substantive changes are not open for comment under this proposed rule. We seek comment on proposed additions and proposed removals under applicable specialty sets in Table Group B of this Appendix.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Allergy/Immunology specialty set.

B.1. Allergy/Immunology							
PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* § ! (Outcome)	N/A / N/A	338	N/A	MIPS CQMs Specifications	Outcome	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	N/A / N/A	340	N/A	MIPS CQMs Specifications	Process	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration

B.1. Allergy/Immunology							
PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Allergy/Immunology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of drivers of health (DOH) data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10- or 13-item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Allergy/Immunology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET													
Indicator						**CBE # / eCQM CBE #**		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						to follow-up measurement.								

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ALLERGY/IMMUNOLOGY SPECIALTY SET Note: In this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set and this specialty set has no proposed changes.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQMs Specifications	Outcome	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQMs Specifications	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQMs Specifications	Process	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQMs Specifications	Process	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Audiology specialty set.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	2152/ N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.3. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	317	CMS2 2v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set. We agree with interested parties' feedback that adding this measure to this specialty set would help to broaden the patient population being screened for high blood pressure. There is known risk of adverse effects on the auditory system due to high blood pressure making this an important aspect of care for audiologists. Given the close correlation of adverse effects on the auditory system due to hypertension, interdisciplinary care is vital, and it should be the responsibility of all clinician types to address health promotion and wellness, and prevention, delay, or management of acute or chronic diseases and conditions. This measure would support the comprehensive evaluation of compliance of screening for and proper treatment of high blood pressure that can improve quality care and prevent disease for the general population. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule.

B.3. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Audiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Cardiology specialty set.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS13 5v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS14 5v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS14 4v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – And • Most recent tobacco status is Tobacco Free – And • Daily Aspirin or Other Antiplatelet Unless Contraindicated – And Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: • Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Cardiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for

B.4a. Cardiology

MEASURES PROPOSED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET														
Indicator			**CBE # / eCQM CBE #**					**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
														rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months**: The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Cardiology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE CARDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set and this specialty set has no proposed changes.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Certified Nurse Midwife specialty set.

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	475	CMS349v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

B.5. Certified Nurse Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**CVD Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine	We propose to include this measure in the Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. This measure fills a high priority clinical gap area under the wellness and prevention domain for maternal health by addressing screening and care for pregnant/postpartum patients by assessing for a standardized CVD risk assessment for this high-risk population cared for by clinicians in this specialty. Given the close correlation of CVD risks and pregnant/postpartum patients, interdisciplinary care is vital. The addition of this quality measure to this specialty set would incentivize thorough assessment for patient risk and increase education and awareness in this population. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Certified Nurse Midwife specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Safety)			N/A /	TBD	N/A	MIPS CQM	Process	**Initiation,**	American	We propose to include this measure in the

	N/A			s Specifications		**Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	Psychiatric Association	Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A /	TBD	N/A	MIPS CQM	Patient-	**Reduction in**	American	We propose to include this measure in the

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
	N/A			s Specifications	Reported Outcome-Based Performance Measure	**Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	Psychiatric Association	Certified Nurse Midwife specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty would reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Chiropractic Medicine specialty set.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.6. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Chiropractic Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Clinical Social Work specialty set.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149 v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159 v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Patient Safety)	N/A / N/A	382	CMS177 v12	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance	We propose to include this measure in the Clinical Social Work specialty set as it would be clinically relevant to this clinician type. We agree with interested parties' feedback that this measure would be beneficial for clinical social workers to address the complex psychosocial challenges that accompany those with substance use disorders. Behavioral health clinicians, such as clinical social workers, are instrumental in ensuring that services address the needs of these individuals. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET														
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Clinical Social Work specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type as this profession has historically addressed social needs through screening and evaluation, providing referrals, and connecting patients to community services and falls within their scope of care. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.				

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Clinical Social Work specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type. Clinical social workers are vital in helping those with mental health and substance use disorders (SUD). Social work practice is in a unique position to influence the delivery of services by addressing the acute and chronic needs of clients with SUDs, including co-occurring disorders and polysubstance patterns. By developing and applying evidence-informed approaches that incorporate established interventions and evolving techniques based on emerging research findings, clinical social workers can markedly improve treatment services for clients and their families. The measure being added to this specialty set

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**		**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
									would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.	

! (Safety)	N/A/N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Clinical Social Worker specialty set as this measure would be clinically relevant to this clinician type. We agree with interested parties' feedback that incorporating this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and adding it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**		**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
									substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SPECIALTY SET										
Indicator	**CBE # / eCQM CBE #**	**Quality #**		**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Outcome)		N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Clinical Social Work specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type. The interested parties noted that this measure could provide meaningful data that could be used to support evidence-based treatment and promote better quality of care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CLINICAL SOCIAL WORK SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dentistry specialty set.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v12	eCQM Specifications	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months to 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v13	eCQM Specifications	Process	**Primary Caries Prevention Intervention as Offered by Dentists:** Percentage of children, 6 months to 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dermatology specialty set.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
	N/A/ N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician- or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	485	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	486	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.	American Academy of Dermatology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.9. Dermatology

MEASURES PROPOSED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Dermatology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.9. Dermatology

MEASURES PROPOSED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Dermatology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE DERMATOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.									
CBE # / eCQM CBE #					**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A					138	N/A	MIPS CQMs Specifications	Process	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.					National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Diagnostic Radiology specialty set.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.10. Diagnostic Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Outcome)				3633e / N/A				TBD	CMS1056v1	eCQM Specifications	Intermediate Outcome	**Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level):** This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical Indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)	We propose to include this measure in the Diagnostic Radiology specialty set as it would be clinically relevant to this clinician type. This measure would provide radiologists with a clinically relevant outcome measure within MIPS and meets the high priority definition for MIPS reporting as an outcome and patient safety measure. It aligns with numerous consensus-based clinical recommendations and guidelines and is also consistent with the CMS emphasis on expanding digital quality measures with reduction in clinician burden. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.1 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or	OCHIN	We propose to include this measure in the Diagnostic Radiology specialty set as it's clinically screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data					

B.10. Diagnostic Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE DIAGNOSTIC RADIOLOGY SPECIALTY SET														
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.		capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association/ National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Emergency Medicine specialty set.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069/ N/A	065	CMS154v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
*	N/A / N/A	254	N/A	MIPS CQMs Specifications	Process	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A / N/A	317	CMS22v1 2	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
! (Efficiency)	N/A / N/A	416	N/A	MIPS CQMs Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET													
Indicator					**CBE # / eCQM CBE #**			**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Emergency Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.							

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE EMERGENCY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE EMERGENCY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	107	CMS161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Endocrinology specialty set.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347 v7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
	N/A / N/A	462	CMS645 v7	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.12. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Endocrinology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.12. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10–- or 13–- item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Endocrinology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ENDOCRINOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.						

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Family Medicine specialty set.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v 12	eCQM Specifications	Process	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
! (Opioid)	N/A / N/A	305	CMS137v 12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	309	CMS124v 12	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139v 12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* § ! (Outcome)	N/A / N/A	338	N/A	MIPS CQMs Specifications	Outcome	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v 12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A / N/A	374	CMS50v1 2	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	377	CMS90v1 3	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v 7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – And • Most recent tobacco status is Tobacco Free – And • Daily Aspirin or Other Antiplatelet Unless Contraindicated – And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality
* § ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249v 6	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS349v 6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771v 5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Outcome)	3568 / N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	488	CMS951v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models. In addition, it can facilitate and improve effective patient-provider communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
			N/A /	TBD	N/A	MIPS CQMs	Process	**Preventive Care and Wellness**	Centers for Medic	We propose to include this measure in the Family

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
	N/A			Specifications		**(composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	are and Medicaid Services	Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Family Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Meas	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use	American Psychiatric Association	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. This measure addresses a high priority specialty area and high priority clinical

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
					ure	disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.		condition for MIPS. It's an important comprehensive PRO-PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Family Medicine specialty set would reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET															
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version" or "Since Last Visit", within 120 days after an index assessment.	American Psychiatric Association								We propose to include this measure in the Family Medicine specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty would reinforce our commitment that all clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #		Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	107	CMS161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
2372 / N/A	112	CMS 125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
0034 / N/A	113	CMS 130v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the *Family Medicine* specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.					

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the Family Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Gastroenterology specialty set.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* §	NA / N/A	275	N/A	MIPS CQMs Specifications	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association
* ! (Equity	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.14. Gastroenterology

MEASURES PROPOSED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Gastroenterology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.14. Gastroenterology

MEASURES PROPOSED FOR **ADDITION** TO THE GASTROENTEROLOGY SPECIALTY SET														
Indicator					**CBE # / eCQM CBE #**			**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10–- or 13–- item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia							We propose to include this measure in the Gastroenterology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GASTROENTEROLOGY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed General Surgery specialty set.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.15. General Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE GENERAL SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the General Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GENERAL SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Geriatrics specialty set.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149 v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	0101 / N/A	318	CMS139 v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159 v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771 v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
* ! (Equity	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of (CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Geriatrics specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.16. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Geriatrics specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GERIATRICS SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	226	CMS 138v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the Geriatrics specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Hospitalists specialty set.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* §	N/A / N/A	205	N/A	MIPS CQMs Specifications	Process	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS117 v12	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three Hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one Hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	338	N/A	MIPS CQMs Specifications	Outcome	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	N/A / N/A	340	N/A	MIPS CQMs Specifications	Process	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
* §	N/A / N/A	475	CMS349 v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
						difficulties, and interpersonal safety.	
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.18. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Infectious Disease specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity within all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Internal Medicine specialty set.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128 v12	eCQM Specifications	Process	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	236	CMS165 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
! (Opioid)	N/A / N/A	305	CMS137 v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124 v12	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139 v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	338	N/A	MIPS CQMs Specifications	Outcome	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159 v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A / N/A	374	CMS50v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	377	CMS90v 13	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.	American Gastroenterological Association

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the measurement period: • All patients with an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or ever had an ASCVD procedure; OR • Patients aged ≥ 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
* § ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249 v6	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS349 v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771 v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3568 / N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This measure is predicated on existing guidelines and conceptual models. In addition, it can facilitate and improve effective patient-provider communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. The measure being added to

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specif	Process	**Connection to Community Service Provider:**	OCHIN	We propose to include this measure in the Internal

				ication s		Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.		Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

B.19. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. This measure addresses a high priority specialty area and high priority clinical condition for the MIPS. It's an important comprehensive PRO-PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Internal Medicine specialty set would reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**		**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Outcome)		N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10– or 13– item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

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MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET													
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Internal Medicine specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

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PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.	
N/A / N/A		107	CMS 161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

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PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the Internal Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.												
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the Internal Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.						

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.	

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
CBE # / eCQM CBE #		**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.		

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Interventional Radiology specialty set.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.20. Interventional Radiology

MEASURES PROPOSED FOR **ADDITION** TO THE INTERVENTIONAL RADIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Interventional Radiology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Mental/Behavioral Health and Psychiatry specialty set.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v12	eCQM Specifications	Process	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 2872e	281	CMS149v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive	Centers for Medicare and Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	366	CMS13 6v13	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS15 9v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Patient Safety)	N/A / N/A	382	CMS17 7v12	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**

! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or**	American Psychiatric Association	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it would be clinically relevant to this clinician type. This measure

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
					Performance Measure	**Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.		addresses a high priority specialty and high priority clinical condition for the MIPS. It's an important comprehensive PRO- PM encompassing a broad behavioral health patient population. It utilizes a measurement-based care framework for implementation across various settings and populations. This measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. Adding this measure to the Mental/ Behavioral Health specialty set would reinforce the important role this clinician type plays in addressing patient mental health and substance use disorders. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET															
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.						

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Mental/Behavioral Health and Psychiatry specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and SUD. The addition of this quality measure for this specialty would reinforce our commitment that all

B.21. Mental/Behavioral Health and Psychiatry

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**	
								clinicians should be actively engaging in addressing mental health and SUDs across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.	

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	107	CMS161v12	eCQM Specifications	Process	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.	Mathematica	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nephrology specialty set.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139 v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQMs Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**First Year Standardized Waitlist Ratio (FYSWR):** The number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75, and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The measure is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, adjusted for age, patient comorbidities, and other risk factors at incidence of dialysis.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nephrology specialty set as it would be clinically relevant to this clinician type. The measure's intended objective consists of improving the overall health of patients on dialysis, with Nephrologists at the forefront of caring for this patient population. Clinicians within this specialty are responsible for the education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.4 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	Percentage of **Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW):** The percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). Results are averaged across patients prevalent on the last day of each month during the reporting year. The measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nephrology specialty set as would be clinically relevant to this clinician type. The maintenance of end stage renal disease patients on active status on the waitlist is additionally important given demonstrated disparities and positive association with subsequent transplantation. These practices are important for Nephrologists who are at the forefront of caring for this patient population. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Nephrology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Nephrology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurology specialty set.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
	N/A / 2872e	281	CMS149v 12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.23. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Neurology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SPECIALTY SET														
Indicator							**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia							We propose to include this measure in the Neurology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEUROLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurosurgical specialty set.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.24. Neurosurgical

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROSURGICAL SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Neurosurgical specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nutrition/Dietician specialty set.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS155 v12	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** • Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation • Percentage of patients with counseling for nutrition • Percentage of patients with counseling for physical activity	National Committee for Quality Assurance

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set. We agree with interested parties' feedback that depression continues to be a major public health concern and all Medicare clinicians should be doing their part to address the issue. Screening for depression is often a routine part of the comprehensive nutrition assessment performed by Registered Dieticians/ Nutritionists (RDNs) as nutrition status is closely linked to mental health. Optimizing the nutrition status of an individual with mental illness has been shown to improve both cognitive and emotional functioning. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Nutrition/Dietician specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NUTRITION/DIETICIAN SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Obstetrics/Gynecology specialty set.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	309	CMS124v 12	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v 12	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
* § ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQMs Specifications	Process	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249v6	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS349v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. This measure fills a high priority clinical gap area under the wellness and prevention domain for maternal health by addressing screening and care for pregnant/postpartum patients by assessing for a standardized CVD risk assessment for this high-risk population cared for by clinicians in this specialty. Given the close correlation of CVD risks and pregnant/postpartum patients, interdisciplinary care is vital. The addition of this quality measure to this specialty set would incentivize thorough assessment for patient risk and increase education and awareness in this population. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET														
Indicator			**CBE # / eCQM CBE #**					**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Obstetrics/Gynecology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.													

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale,

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								including clinical evidence supporting the inclusion of this measure in MIPS.

! (Safety)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. The incorporation of this measure in this specialty set would help promote interventions and best practices that are effective at symptoms reduction and improving functional status and quality of life. This measure is a high priority area for MIPS and by adding the measure to this specialty set it would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder, while also reinforcing our commitment that all clinicians should be actively engaging in addressing mental

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.13 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit', within 120 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Obstetrics/Gynecology specialty set as it would be clinically relevant to this clinician type. This patient reported outcome measure focuses on mental health and substance use disorder (SUD) and the reduction of suicidal ideation, conceptually addressing behavioral health which are a CMS high priority area. Incorporating this clinical outcome measure in this specialty set would encourage measure adoption which would support clinician adherence to clinical guidelines, leading to better symptom control and improved quality of life for patients affected by mental health and substance use disorder. The addition of this quality measure for this specialty would reinforce our commitment that all clinicians

B.26. Obstetrics/Gynecology

MEASURES PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**	
								should be actively engaging in addressing mental health and substance use disorders across the care continuum. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.14 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.	

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
2372 / N/A	112	CMS 125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the Obstetrics/Gynecology specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.												
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the *Obstetrics/Gynecology* specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.					
N/A / N/A	402						N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.	

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Oncology/Hematology specialty set.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v1 3	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	0384 / 0384e	143	CMS157 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v 12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPs Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645 v7	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	490	N/A	MIPS CQMs Specifications	Process	**Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care provider and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We propose to include this measure in the Oncology/ Hematology specialty set as it would be clinically relevant to this clinician type. This patient-reported outcome measure would help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with his or her clinician. Patients feeling heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Oncology/Hematology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Oncology/Hematology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Radiation Oncology specialty set.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	102	CMS12 9v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	0384 / 0384e	143	CMS15 7v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.28. Ophthalmology/Optometry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Ophthalmology/Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Ophthalmology/Optometry specialty set.

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 0086e	012	CMS143v12	eCQM Specifications	Process	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS142v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Ophthalmology/Optometry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET																
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy:** Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.	American Society of Retina Specialists								We propose to include this measure in the Ophthalmology and Optometry specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given the high rates that patients are assessed, treated, and managed for this condition in the Ophthalmology and Optometry care setting. This measure addresses the MIPS priority area of patient safety. This measure would help to incentivize timely initiation of the appropriate screening for these patients and ensure there is a plan of care for elevated IOP following intravitreal or periocular steroid therapy. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.8 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks	American Society of Retina Specialists	We propose to include this measure in the Ophthalmology and Optometry specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given the high rates that patients are assessed, treated, and managed for this condition in the Ophthalmology and Optometry care setting. This measure is guideline based and addresses the MIPS priority area of patient safety. It's also linked to health outcomes by appropriate care for acute PVD, which can prevent retinal tears. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.9 of this Appendix for rationale, including clinical evidence supporting the inclusion of this

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								measure in MIPS.

B.28. Ophthalmology/Optometry

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.10 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.28. Ophthalmology/Optometry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OPHTHALMOLOGY/OPTOMETRY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0087 / N/A	014	N/A	MIPS CQMs Specifications	Process	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.29. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Orthopedic Surgery specialty set.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v12	eCQM Specifications	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270 – 365 days after the surgery.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers** of **Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Orthopedic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.30. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Otolaryngology specialty set.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Service
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicin
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicin

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Service
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Service
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.30. Otolaryngology

MEASURES PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Otolaryngology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.31. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set and this specialty set has no proposed changes.

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQMs Specifications	Process	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma:** Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both	College of American Pathologists

B.32. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pediatrics specialty set.

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	205	N/A	MIPS CQMs Specifications	Process	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS155v12	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS117v12	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three Hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one Hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	305	CMS137v12	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v12	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	366	CMS136v13	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v12	eCQM Specifications, MIPS CQMs Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Patient Safety)	N/A / N/A	382	CMS177v12	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.32. Pediatrics

MEASURES PROPOSED FOR **ADDITION** TO THE PEDIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We propose to include this measure in the Pediatrics specialty set. Updates are being proposed to measure Q226 to now include patients 12 years of age and older. Therefore, screening for tobacco use and cessation intervention would be an important measure for the pediatric clinician type to utilize. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.32. Pediatrics

MEASURES PROPOSED FOR **ADDITION** TO THE PEDIATRICS SPECIALTY SET																
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Pediatrics specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.								

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PEDIATRICS SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	**Follow-Up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PEDIATRICS SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

B.33. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Medicine specialty set.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.33. Physical Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Physical Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PHYSICAL MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.34. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient- Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v12	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers** of **Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology	We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type. Occupational therapy services enable clients to participate in their everyday life occupations in their desired roles, contexts, and life situations through evaluation and treatment related to basic activities of daily living and instrumental activities of daily living. Occupational therapy practitioners use their knowledge and skills to help clients conduct or resume daily life occupations that support function and health throughout the lifespan, including patients with dementia and their caregivers. The addition of this quality measure in this specialty set would make room for more clinician choice by making more measures available that are reflective of the services delivered to this patient population. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Physical Therapy/ Occupational Therapy specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association	We propose to include this measure in the Physical Therapy/ Occupational Therapy (OT) specialty set as it would be clinically relevant to this clinician type. We agree with interested parties' feedback that this measure would help to broaden the patient population being assessed for mental and/or substance use disorders and their maintenance and recovery. In addition, Occupational therapy practitioners provide services to people across the lifespan who experience a range of mental health and ill health based on genetic predisposition and/or life stressors (e.g., disability, injury, trauma). Occupational therapy is used to help support people with mental illness in skill development, activity engagement, and with

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**		**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
										meeting individual recovery goals under an OT Plan of Care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.11 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.34. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET														
Indicator		**CBE # / eCQM CBE #**						**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Physical Therapy/ Occupational Therapy specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.					

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal from the Physical Therapy/Occupational Therapy specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. PT/OT applicable coding has not been added to this measure, so we are proposing to remove this measure from this specialty set.
N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.35. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Plastic Surgery specialty set.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.35. Plastic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE PLASTIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Plastic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PLASTIC SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.36. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Podiatry specialty set.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139v12	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.36. Podiatry

MEASURES PROPOSED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! Outcome	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Podiatry specialty set as it would be clinically relevant to this clinician type. The addition of this measure would provide this specialty the opportunity to report on an important PRO-PM that would align with their scope of care consisting of the treatment of the lower extremity. Functional deficits are common in the general population and are costly to the individual, their family and society, and improving functional status has been associated with greater quality of life, self-efficacy, improved financial well-being and lower future medical costs (*https://fotoinc.com/science-of-foto/nqf-measure-specifications/*). Predictive modeling allows for patient-level predictions to help guide treatment decision making and expectations for recovery.

B.36. Podiatry

MEASURES PROPOSED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET															
Indicator								**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services								We propose to include this measure in the Podiatry specialty set. The addition of this measure to this specialty set would help to broaden the patient population being screened for high blood pressure. There is known risk of adverse effects on the circulatory system due to high blood pressure making this an important aspect of care for podiatrists. Hypertension is often related to atherosclerosis and this buildup of plaque in blood vessels can lead to decreased circulation and peripheral arterial disease (PAD) (*https://www.apma.org/hypertension*). Patients with decreased circulation in their lower extremities may develop ulcerations that can lead to amputations. Given the close correlation of hypertension and decreased circulation in lower extremities, interdisciplinary care is vital and should be the responsibility of all clinician types. The addition of this measure to the Podiatry specialty set would help to encourage the comprehensive evaluation of compliance of screening for and proper treatment of high blood pressure that can improve quality care and prevent disease for the general population.

! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons	We propose to include this measure in the Podiatry specialty set as it would be clinically relevant to this clinician type. Patients undergoing podiatric surgery should receive a thorough perioperative evaluation. Medical "clearance" is no longer sufficient; rather, formal risk assessment should be performed, and risk-reducing strategies communicated. A collaborative, multidisciplinary approach is generally most appropriate, however, expertise and training in this critical dimension of clinical practice varies. Thus, podiatrists should develop independent competence in perioperative evaluation to ensure optimal care for their patients. In preparation for elective foot and ankle surgery, the podiatric surgeon often will refer the patient for a preoperative evaluation. Surgeons rely on the input of that consultant to provide a determination as to the operative risk for the patient (*https://pubmed.ncbi.nlm.nih.gov/12776978/*).
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen	OCHIN	We propose to include this measure in the Podiatry specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with

B.36. Podiatry

MEASURES PROPOSED FOR **ADDITION** TO THE PODIATRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.		all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10- or 13-item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Podiatry specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PODIATRY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.37. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Preventive Medicine specialty set.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQMs Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
! (Care Coordination)	N/A / N/A	374	CMS50v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v7	eCQM Specifications, MIPS CQMs Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	475	CMS349 v6	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951 v2	eCQM specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services	We propose to include this measure in the Preventive Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this quality measure to this specialty set would reinforce our commitment that all clinicians should be actively engaging in activities that address preventive care and wellness and is in alignment with our priorities to support overall patient health. The measure would set a more stringent performance standard by requiring a set of preventive care for the general population in one composite measure and aligns with evidence-based recommendations. The measure would help incentivize a more broadly encompassing preventive care assessment to guide clinicians. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Preventive Medicine specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Preventive Medicine specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
2372 / N/A	112	CMS125v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Breast Cancer Screening:** Percentage of women 50 – 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
0034 / N/A	113	CMS130v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Colorectal Cancer Screening:** Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group CC of this Appendix for rationale.
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.													
CBE # / eCQM CBE #							**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal from the *Preventive Medicine* specialty set beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is proposed to be included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix). The inclusion of both quality measures in this specialty set would be duplicative.						
N/A / N/A							317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from the Preventive Medicine specialty set beginning with the CY 2024 performance period/2026 MIPS payment year.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.38. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pulmonology specialty set.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
! (Care Coordination)	N/A / N/A	374	CMS50v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.38. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Pulmonology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule. Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.38. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Pulmonology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PULMONOLOGY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.39. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Rheumatology specialty set.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive	Centers for Medicare & Medicaid Services

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee Quality Assurance

B.39. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Rheumatology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.39. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SPECIALTY SET														
Indicator				**CBE # / eCQM CBE #**				**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia							We propose to include this measure in the Rheumatology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE RHEUMATOLOGY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.40. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Skilled Nursing Facility specialty set.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v 12	eCQM Specifications, MIPS CQMs Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	326	N/A	MIPS CQMs Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQMs Specifications	Process	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Skilled Nursing Facility specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.41. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Speech Language Pathology specialty set.

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.41. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology	We propose to include this measure in the Speech Language Pathology specialty set. We agree with interested parties' feedback that SLPs are keenly interested in a measure set that includes quality measures that are more reflective of the types of clinical conditions they treat. While the diagnosis of Parkinson's disease is made by a medical team, SLPs are trained to assess cognitive-communication deficits related to this condition, and to identify cultural, linguistic, and environmental influences that have an impact on functioning. The services provided by SLPs contribute to improving the safety and well-being of the individual. Therefore, it would be important to consider SLPs as an integral member of the clinical care team working with patients diagnosed with Parkinson's and include this measure in the speech-language pathology specialty measure set. The addition of this quality measure in this specialty set would make room for more clinician choice by making more measures available that are reflective of the services delivered to this patient population. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.41. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set as patients' social drivers of health can be a key component to a patient achieving health equity within all clinical settings and clinician types. We agree with interested parties' feedback that SLPs are committed to addressing health equity and play a key role in screening individuals for social risks. When factors are identified, SLPs consider them when establishing a care plan and modifications are made to create achievable, sustainable, and functional goals that are patient-centered. In response to the interested parties' feedback, we are proposing to add this measure to this specialty set if all proposed measures for the specialty set are finalized. This is a screening data collection measure and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Currently, if all proposed measures for this specialty set are finalized, the SLP specialty set would contain 11 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. Under MIPS, clinicians have the flexibility to choose to report the measures that would work best for their scope of practice and clinical workflow. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule.

B.41. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET									
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**		**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Speech Language Pathology specialty set. We agree with interested parties' feedback that this measure would be clinically relevant to this clinician type as this profession has historically addressed social needs through screening and evaluation, providing referrals, and connecting patients to community services and falls within their scope of care. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. This is a screening measure requiring a connection to the CSP, and is voluntary; therefore, clinicians have the flexibility to choose to report this measure and it only looks at the screening of patients. Currently, if all proposed measures for this specialty set are finalized, the Speech Language Pathology specialty set would contain 11 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care. Under MIPS, clinicians have the flexibility to choose to report the measures that would work best for their scope of practice and clinical workflow. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.42. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Thoracic Surgery specialty set.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
* §	N/A / N/A	226	CMS13 8v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50 v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.42. Thoracic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE THORACIC SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Thoracic Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE THORACIC SURGERY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.43. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urgent Care specialty set.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

MEASURES PROPOSED FOR **ADDITION** TO THE URGENT CARE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Urgent Care specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE URGENT CARE SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.

B.44. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urology specialty set.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v 13	eCQM Specifications, MIPS CQMs Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer	Centers for Medicare & Medicaid Services
*	N/A / N/A	104	N/A	MIPS CQMs Specifications	Process	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022/ N/A	238	CMS156v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQMs Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216/ N/A	457	N/A	MIPS CQMs Specifications	Outcome	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A / N/A	462	CMS645v7	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
! (Outcome)	N/A / N/A	476	CMS771v5	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A/ N/A	481	CMS646v 4	eCQM Specifications	Process	**Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	488	CMS951v 2	eCQM Specifications, MIPS CQMs Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.	National Kidney Foundation

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Urology specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data, which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on applicable coding updates to the measure by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 - or 13 - item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We propose to include this measure in the Urology specialty set as it would be clinically relevant to this clinician type. The addition of this measure to this specialty set would be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It's utilized within the U.S. and internationally in research and has also been shown to be valid and reliable in different clinical settings and under different payment models. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.12 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE UROLOGY SPECIALTY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	128	CMS69 v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.

B.45. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix to this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Vascular Surgery specialty set.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v13	eCQM Specifications, MIPS CQMs Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	226	CMS138v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	NA / NA	260	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
*	N/A / N/A	317	CMS22v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A / N/A	374	CMS50v12	eCQM Specifications, MIPS CQMs Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
* ! (Equity)	N/A / N/A	487	N/A	MIPS CQMs Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.45. Vascular Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE VASCULAR SURGERY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Equity)	N/A / N/A	TBD	N/A	MIPS CQMs Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health-related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN	We propose to include this measure in the Vascular Surgery specialty set as screening for and working to address patient's HRSNs can be a key component to a patient achieving health equity with all clinical settings and clinician types. This measure addresses our identified social and economic determinants as both a measurement priority and gap and is a central part of our Health Equity strategic plan pillar moving forward. This measure is an important next step for use of DOH data which assists in defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians. Choosing to report this measure would allow data capture to expand beyond assessing health inequities by connecting patients with resources within the scope of MIPS reporting. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2024 PFS final rule. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE VASCULAR SURGERY SPECIALTY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measures set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #							Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A							128	CMS 69v12	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from traditional MIPS beginning with the CY 2024 performance period/2026 MIPS payment year. This measure is included as a component of the proposed Preventive Care and Wellness (composite) measure (See Table A.6 of this Appendix); however, this measure is appropriate and applicable for some MVPs and is therefore proposed for retention for MVP use. See Table Group CC of this Appendix for rationale.
N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the CY 2024 performance period/2026 MIPS payment year. See Table Group C of this Appendix for rationale.						

Table Group C: Previously Finalized Quality Measures Proposed for Removal in the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

In this proposed rule, we propose to remove 12 previously finalized MIPS quality measures from MIPS for the CY 2024 performance period/2026 MIPS payment year and future years. These measures are discussed in detail below. The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discusses our incremental approach to removing process measures.

Under our measure removal criteria, consideration is given to the following, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.*
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- If they do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.
- After factoring in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcomes; consideration of the measure in developing MVPs).
- If we determine the measure is not available for MIPS reporting by or on behalf of all MIPS eligible clinicians.

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion that we use for the removal of measures includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent.

For a measure that is proposed for removal due to criteria relating to the benchmark and performance data, further information regarding MIPS benchmarking data can be located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip*.

C.1. Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
CBE # / eCQM CBE #:	0087 / N/A
Quality #:	014
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 month performance period.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.2. Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	0654 / N/A
Quality #:	093
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.3. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	107
CMS eCQM ID:	CMS161v12
Collection Type:	eCQM Specifications
Measure Description:	Percentage of all patient visits for those patients that turn 18 or older during the measurement period in which a new or recurrent diagnosis of major depressive disorder (MDD) was identified and a suicide risk assessment was completed during the visit.
Measure Steward:	Mathematica
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk measure being proposed in Table A.13 of this Appendix. Measure Q107 is specific to major depressive disorder whereas the new measure would include patients with other behavioral health conditions who are at risk of suicide. Furthermore, the proposed new measure represents a high priority area for MIPS: mental health. It focuses on a care process that is directly designed to mitigate suicide risk, as opposed to just completing the screening. Studies have shown that clinical interventions aimed at suicide prevention, such as initiating and reviewing a suicide safety plan with a patient at risk of suicide, is a proxy for the clinical outcome of a reduction in suicides, suicide attempts, and suicidal ideation (*https://pubmed.ncbi.nlm.nih.gov/29998307/*).
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the CY 2024 PFS final rule, we propose to apply the following substantive change to the measure specifications: 1) the measure description, initial patient population and guidance would be updated so that the age description in the narrative matches the Clinical Quality Language (CQL) logic of capturing patients who are 17 years and older. This proposal ensures the measure is implemented as specified, and the correct patient population is being captured. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix. The substantive changes outlined above would be applied to the measure specifications.

C.4. Preventive Care and Screening: Influenza Immunization

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	110
CMS eCQM ID:	CMS147v13
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 6 months and older seen for a visit during the measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to a more robust measure Q493: Adult Immunization Status. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q110 only focuses on the administration of the influenza immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Furthermore, the measure is currently only available for use within MVPs; however, based upon interested party feedback, measure Q493 is being proposed as a replacement for those MVPs that contain measure Q110. This measure would remain for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the CY 2024 PFS final rule, we propose to apply the following substantive change to the measure specifications: 1) denominator exclusion for all collection types would be updated to include anaphylaxis due to the vaccine as there is new coding available to capture this data. It is clinically appropriate and prudent to refrain from administering the vaccine to patients who experienced anaphylaxis with a previous vaccine administration. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix. The substantive changes outlined above would be applied to the measure specifications.

C.5. Pneumococcal Vaccination Status for Older Adults

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	111
CMS eCQM ID:	CMS127v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 66 years of age and older who have received a pneumococcal vaccine.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to a more robust measure Q493: Adult Immunization Status. This measure's clinical concept is included in the Adult Immunization Status measure. Measure Q111 only focuses on the administration of the pneumococcal immunization rather than providing a comprehensive evaluation based on all the recommended age-appropriate immunizations that promote well-being. Furthermore, the measure is currently only available for use within MVPs; however, based upon interested party feedback, measure Q493 is being proposed as a replacement for those MVPs that contain measure Q111.
In the Circumstance the Measure is Retained	If the measure is not finalized for removal in the CY 2024 PFS final rule, we propose to apply the following substantive changes to the measure specifications: 1) for the eCQM Specifications collection type, the denominator exclusion would be updated to include anaphylaxis any time before the end of the measurement period due to new coding availability to capture this data; 2) for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types, the denominator exclusions for active chemotherapy, bone marrow transplant and history of immunocompromising conditions would be removed; and 3) for all collection types, the initial patient population would be changed from 66 years of age and older to 65 years of age and older while the numerator criteria lookback period would be extended to the 19th birthday for pneumococcal vaccination. These updates would lend to better alignment with the most recent ACIP guidelines *(https://www.cdc.gov/vaccines/vpd/pneumo/hcp/recommendations.html)*. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix. The substantive changes outlined above would be applied to the measure specifications.

C.6. Melanoma: Coordination of Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	138
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.7. Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	147
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.
Measure Steward:	Society of Nuclear Medicine and Molecular Imaging
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.8. Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	283
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.9. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	324
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because the quality action being measured is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 0.81 percent for the MIPS CQMs Specifications collection type. As such, the MIPS CQMs Specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2272/2023%20Quality%20Benchmarks.zip.*
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.10. Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
CBE # / eCQM CBE #:	0576 / N/A
Quality #:	391
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because we received feedback from interested parties that it is analytically challenging to implement this measure at the clinician level. The quality action of this measure is to ensure that patients discharged from an acute setting have outpatient follow ups. However, clinicians have provided feedback that patients who receive inpatient care, and are denominator eligible for this measure, may not always seek follow-up care within the inpatient clinician's health system which limits the clinician's or group's ability to document adequate follow up to outpatient encounters. This limitation makes it difficult to attribute the required numerator actions back to the accountable clinician, creating undue burden for MIPS eligible clinicians.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.11. Tobacco Use and Help with Quitting Among Adolescents

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	402
CMS eCQM ID:	N/A
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. We are proposing in Table D.22 of this Appendix substantive changes to measure Q226 that would broaden the denominator by lowering the age to 12 years old and would therefore capture the denominator-eligible patient population for this measure.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

C.12. Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	436
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.
Measure Steward:	American College of Radiology/ American Medical Association/ National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from MIPS because this measure is duplicative to the measure Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) being proposed in Table A.1 of this Appendix. This new measure is an outcome and digital measure which supports MIPS' focus on quality measures that assess outcomes and reduce clinician burden. The focus of this measure is to reduce radiation doses from computerized tomography (CT) scans, which may increase the risk of cancer. This new measure is more robust than measure Q436 which represents a process measure.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure. If the measure is not finalized for removal in the CY 2024 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.

Table Group CC: Proposed Partial Removal of Three Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Proposed Retention of These Three Measures for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

Beginning with the CY 2024 performance period/2026 MIPS payment year and future years, we propose to maintain 3 quality measures: Q112: Breast Cancer Screening; Q113: Colorectal Cancer Screening; and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan for MVP development and implementation (and maintain quality measures Q112 and Q113 for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP). The clinical concepts represented by these MIPS quality measures would support some specialties in a more targeted approach rather than the broader clinical concept of preventive screenings represented within the proposed Preventive Care and Wellness (composite) measure proposed under Table A.6 of Appendix 1: MIPS Quality Measures. The tables within this section offer the rationale for the proposal to partially remove quality measures Q112, Q113, and Q128, in which such quality measures are proposed for removal from traditional MIPS but retained for use in MVPs.

Therefore, we are proposing to remove the three aforementioned previously finalized quality measures from traditional MIPS due to the proposal of adding the Preventive Care and Wellness (composite) measure in Table A.6 of Appendix 1: MIPS Quality Measures, which includes the concepts of quality measures Q112, Q113, and Q128 as part of the proposed composite Preventive Care and Wellness measure, and retain measures Q112, Q113, and Q128 for use in MVPs (and retain measures Q112 and Q113 for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP as discussed in section III.G.2.c.(2) of this proposed rule; see Table Group E of this Appendix for the proposed changes to quality measures Q112 and Q113 available within the CMS Web Interface collection type).

Furthermore, measure Q112 is proposed as an available measure within the proposed Focusing on Women's Health MVP (see Appendix 3: MVP Inventory Table A.1).

Measure Q128 is proposed for removal from traditional MIPS with proposal for retention in MVPs under Table CC.3 of this Appendix. It is noted that measure Q128 is being proposed as an available measure within the following two proposed MVPs: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP and Rehabilitative Support for Musculoskeletal Care MVP (see Appendix 3: MVP Inventory Tables A.2 and A.5). Quality measure Q128 is currently an available measure within the following 2 previously finalized MVPs: Advancing Care for Heart Disease MVP and Improving Care for Lower Extremity Joint Repair MVP (see Appendix 3: MVP Inventory Tables B.5 and B.8).

We request comments on this proposal.

CC.1. Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of women 50-74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we propose a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q112 only focuses on a single clinical concept of women who have had a mammogram screening for breast cancer rather than a comprehensive preventive care and wellness approach; however, the clinical quality action assessed within measure Q112 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap within the quality performance category of these MVPs. Therefore, we propose the removal of this measure from traditional MIPS but propose retention of this measure for use in relevant MVPs. Measure Q112 has already been finalized in the Promoting Wellness MVP but is proposed for removal from that MVP due to the proposal of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and proposal of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11). Measure Q112 is currently proposed as a quality measure within the proposed Focusing on Women's Health MVP (see Appendix 3: MVP Inventory Table A.1). It is also part of the CQMC, Adult Universal Core Set, and in alignment across multiple CMS quality reporting programs. This measure would remain for purposes of the CMS Web Interface collection type available to Share Savings Program ACOs reporting through the APP.
In the Circumstance the Measure is Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix is not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would retain measure Q112 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes proposed for this measure.

CC.2. Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034/ N/A
Quality #:	113
CMS eCQM ID:	CMS130v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we propose a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q113 only focuses on a single clinical concept of patients who have had an appropriate screening for colorectal cancer rather than a comprehensive preventive care and wellness approach; however, the clinical quality action assessed within measure Q113 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap in these identified MVPs. Therefore, we propose the removal of this measure from traditional MIPS but propose retention of this measure for use in relevant MVPs. This measure has previously been finalized in the Promoting Wellness MVP but is proposed for removal from that MVP due to the proposal of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and proposal of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11). This measure would remain available for purposes of the CMS Web Interface collection type available to Shared Savings Program ACOs reporting through the APP.
In the Circumstance the Measure is Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix is not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would retain measure Q113 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes proposed for this measure.

CC.3. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	128
CMS eCQM ID:	CMS69v12
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if the most recent BMI was outside of normal parameters
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from traditional MIPS because we propose a more robust and comprehensive measure under Table A.6: Preventive Care and Wellness (composite) of this Appendix. This clinical concept is included as one of the components of the Preventive Care and Wellness (composite) measure. Measure Q128 only focuses on the clinical concept of a documented BMI and follow-up plan if the BMI was outside of normal parameters, rather than a comprehensive preventive care and wellness approach. However, the clinical quality action assessed within measure Q128 is appropriate and applicable for some MVPs, where other components within the composite measure are not, leaving a potential gap in these identified MVPs. Therefore, we propose the removal of this measure from traditional MIPS but propose retention of this measure for use in relevant MVPs. Measure Q128 is currently proposed as a quality measure for use within two proposed MVPs: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP and Rehabilitative Support for Musculoskeletal Care MVP (see Appendix 3: MVP Inventory Tables A.2 and A.5). Measure Q128 is available within two previously finalized MVPs: Advancing Care for Heart Disease MVP and Improving Care for Lower Extremity Joint Repair MVP (see Appendix 3: MVP Inventory Tables B.5 and B.8). This measure has previously been finalized in the Promoting Wellness MVP but is proposed for removal from that MVP due to the proposal of the Preventive Care and Wellness (composite) measure under Table A.6 of this Appendix and proposal of a consolidated MVP titled Value in Primary Care (see Appendix 3: MVP Inventory Table B.11).
In the Circumstance the Measure is Retained	If measure A.6: Preventive Care and Wellness (composite) of this Appendix is not finalized for the CY 2024 performance period/2026 MIPS payment year and future years, we would retain measure Q128 in traditional MIPS in all applicable specialty sets under Table Group B of this Appendix. See Table Group DD of this Appendix for any substantive changes proposed for this measure.

Table Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

NOTE: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE # / eCQM CBE #.

The D Tables within this proposed rule provide the substantive changes proposed for the quality measures in CY 2024. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2024 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2024 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2025. The 2024 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2024 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2024 quality measure specifications, in the form of an 'Instructions Note' to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only where telehealth encounters previously were not allowed as denominator eligible would the D table corresponding to a measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: For the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface measures as a collection type is only available for APM Entities, specifically Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type is not listed in any table under Table Group D of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this proposed rule. For information regarding proposed changes to the CMS Web Interface measures available for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE # / eCQM CBE #:	0059/ N/A
Quality #:	001
CMS eCQM ID:	CMS122v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to the list of dementia medication exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with the intent of the measure to exclude patients with this condition from the measure.

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
CBE # / eCQM CBE #:	0081 / 0081e
Quality #:	005
CMS eCQM ID:	CMS135v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe."
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) in order to be recognized through electronic capture.

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
CBE # / eCQM CBE #:	0067 / N/A
Quality #:	006
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Substantive Change:	**Updated denominator exception: Removed:** Documentation of system reason(s) for not prescribing aspirin or clopidogrel (e.g., lack of drug availability, other reasons attributable to the health care system). **Updated denominator criteria: Removed:** coding for subsequent myocardial infarction.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the denominator exception for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of these medications. This would also create alignment within the denominator exceptions across all American Heart Association (AHA) measures. We propose to remove patients with subsequent myocardial infarction (MI) from the denominator criteria as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI would already have a diagnosis of CAD from the initial MI. Therefore, these patients would already be correctly included in the denominator eligible patient population.

D.4 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)

Category	Description
CBE # / eCQM CBE #:	0070 / 0070e
Quality #:	007
CMS eCQM ID:	CMS145v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe." **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Removed:** For submission criteria 2: coding for subsequent myocardial infarction For all submission criteria: endoscopic procedures on the heart and pericardium. **Updated denominator exception: For all collection types: Removed:** For all submission criteria: Documentation of system reason(s) for not prescribing beta-blocker therapy (e.g., other reasons attributable to the health care system).
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) to be recognized through electronic capture. We propose to remove patients with subsequent MI from the denominator criteria for the MIPS CQMs Specifications collection type as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI would already have a diagnosis of CAD from the initial MI. Therefore, these patients would already be correctly included in the denominator eligible patient population. Additionally, we propose to remove coding for endoscopic procedures of the heart and pericardium for the MIPS CQMs Specifications collection type as the coding is more related to the harvest of the artery and not the cardiac surgery itself and therefore, these patients may not be appropriate for the quality action. We propose to remove the denominator exception for all collection types for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of beta-blocker therapy. This would also create alignment within the denominator exceptions across all AHA measures.

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
CBE # / eCQM CBE #:	0083 / 0083e
Quality #:	008
CMS eCQM ID:	CMS144v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** In order for the Ejection Fraction result pathway to be recognized as below 40%, the result must be reported as a number with unit of %. A text string of "below 40%" or "ejection fraction between 35 and 40%" will not be recognized through electronic data capture. Although, this criteria can also be met using the Diagnosis pathway if specified as "Moderate or Severe."
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the guidance for the eCQM Specifications collection type by adding documentation requirements for ejection fraction results to ensure the data is being accurately captured. This added statement in the guidance clarifies that the ejection fraction results must be documented as a percentage (for example, 40%) to be recognized through electronica capture.

D.6 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	019
CMS eCQM ID:	CMS142v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**The measure description is revised to read: For the MIPS CQMs Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period. **For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the measurement period. **The measure numerator is revised to read: For the MIPS CQMs Specifications collection type:** Patients with documentation, at least once within the performance period, of the findings of the dilated macular or fundus exam via communication to the physician who manages the patient's diabetic care. **For the eCQM Specifications collection type:** Patients with documentation, at least once within the measurement period, of the findings of the dilated macular or fundus exam via communication to the physician who manages the patient's diabetic care.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description and numerator to clarify that the "reporting period" is the 12-month performance period of January 1st – December 31st and to maintain consistency across measures in MIPS.

D.7 Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	024
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for initial encounters for age-related osteoporosis with current pathological fractures and periprosthetic fractures around internal prosthetic joints.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add coding for initial encounters for age-related or other osteoporosis with current pathological fractures and periprosthetic fractures around internal prosthetic joints to align with codes in the Healthcare Effectiveness Data and Information Set (HEDIS) Fractures Value Set and create consistency in implementation while ensuring the appropriate patient population is identified for numerator compliance assessment.

D.8 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	048
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for physical and occupational therapy clinician types.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add coding for for physical and occupational therapy clinician types as the measure is appropriate and it would be within their scope of care to complete this assessment.

D.9 Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	052
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.
Substantive Change:	**The measure title is revised from 'Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy' to:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic, and were prescribed a long-acting inhaled bronchodilator. **Update instructions: Added:** **This measure will be calculated with 2 performance rates:** 1) Percentage of patients aged 18 years and older with a diagnosis of COPD who have a documented airflow obstruction (FEV1/FVC < 70%) as measured by spirometry. 2) Percentage of patients aged 18 years and older with a diagnosis of COPD who have a documented airflow obstruction (FEV1/FVC < 70%) and are symptomatic, who were prescribed a long-acting inhaled bronchodilator. A simple average, which is the sum of the performance rates divided by the number of performance rates will be used for performance. THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1. Patients diagnosed with COPD with who have documented airflow obstruction (FEV1/FVC < 70%) as measured by spirometry in the medical record. 2. Patients diagnosed with COPD who have documented airflow obstruction (FEV1/FVC < 70%) and are symptomatic, who were prescribed a long-acting bronchodilator. This measure contains two submission criteria which together ensure that the proper evaluation and treatment is provided for patients with COPD and that patients without COPD are not provided inappropriate therapy. Submission Criteria 1 evaluates whether spirometry was performed for patients diagnosed with COPD and results confirming airflow obstruction are documented. Submission Criteria 2 evaluates whether a long-acting inhaled bronchodilator was prescribed for COPD patients who have symptoms. NOTE: Submission of the two performance rates is required for this measure. A simple average, which is the sum of the performance rates divided by the number of the performance rates, will be used to calculate performance. **Updated denominator: Added:** DENOMINATOR (SUBMISSION CRITERIA 1): All patients aged 18 and older with a diagnosis of COPD. **Revised:** DENOMINATOR (SUBMISSION CRITERIA 2): All patients aged 18 years and older with a diagnosis of COPD with spirometry results documented (FEV1/FVC < 70%), and have symptoms (e.g., dyspnea, cough/sputum, wheezing). **Updated denominator criteria: Added:** For Submission Criteria 1: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years on date of encounter AND Diagnosis for COPD AND Patient encounter during the performance period WITHOUT Telehealth Modifier **Revised:** For Submission Criteria 2: Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years on date of encounter AND Diagnosis for COPD AND Spirometry results documented (FEV1/FVC < 70%) AND Patient encounter during the performance period WITHOUT Telehealth Modifier AND Patient has COPD symptoms (e.g., dyspnea, cough/sputum, wheezing) **Updated numerator: Added: For** Submission Criteria 1: Patients with documented spirometry and confirmed airflow obstruction (FEV1/FVC < 70%). **Revised:** For Submission Criteria 2: Symptomatic COPD patients who were prescribed a long-acting inhaled bronchodilator.

Category	Description
	Updated numerator instructions: Added: For Submission Criteria 1: Documentation of spirometry results of (FEV1/FVC < 70%) can take place before the performance period. The intent of Submission Criteria 1 is to ensure accurate diagnosis of COPD in patients with respiratory symptoms such as dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease is appropriate by having documentation of spirometry results of FEV1/FVC < 70%, which is required to make the COPD diagnosis. **Updated numerator note: Added:** For Submission Criteria 1: Denominator Exception(s) are determined on the date of the denominator eligible encounter. If there is a diagnosis of COPD, but there is no documented spirometry within five years of the date of the encounter, and the current spirometry result is ≥70%, an exception may be reported. **Updated numerator options: Added:** For Submission Criteria 1: **Performance Met:** Spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) documented and reviewed. **Denominator Exception:** Documentation of medical reason(s) for not documenting and reviewing spirometry results (e.g., patients with dementia or tracheostomy). **Denominator Exception:** No history of spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) and present spirometry is ≥ 70%. **Denominator Exception:** Documentation of system reason(s) for not documenting and reviewing spirometry results (e.g., spirometry equipment not available at the time of the encounter). **Performance Not Met:** No spirometry results with confirmed airflow obstruction (FEV1/FVC < 70%) documented and/or no spirometry performed with results documented during the encounter. **Revised:** For Submission Criteria 2: **Denominator Exception:** Documentation of medical reason(s) for not prescribing a long-acting inhaled bronchodilator (e.g., patient intolerance or history of side effects). **Denominator Exception:** Documentation of system reason(s) for not prescribing a long-acting inhaled bronchodilator (e.g., cost of treatment or lack of insurance). **Removed:** For Submission Criteria 2: Denominator Exception for patient reason(s).
Measure Steward:	American Thoracic Society
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise this measure to add a submission criteria and performance rate so all patients are assessed for spirometry evaluation to ensure that the proper evaluation and subsequent treatment is provided for the patients with COPD. We propose to add submission criteria one to evaluate whether spirometry was performed and if there were results confirming airflow obstruction. Submission criteria 2 would evaluate whether a long-acting bronchodilator was prescribed for the COPD patient meeting evaluation criteria and having symptoms. The inclusion of submission criteria one "allows potentially wide application of testing to improve recognition and diagnosis of COPD" which is then complimented in submission criteria 2 with the appropriate care of patients diagnosed with COPD.[442] Additionally, we propose to revise the denominator exceptions for submission criteria two to clarify implementation by giving examples of scenarios that meet the denominator exception intent. We propose to remove the denominator exception for patient reason(s) as it is incumbent upon the clinician to educate the patient on the importance of treatment. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

[442] Johns, D. P., Walters, J. A., & Walters, E. H. (2014). Diagnosis and Early Detection of COPD Using Spirometry. Journal of Thoracic Disease, 6(11), 1557–1569. *https://pubmed.ncbi.nlm.nih.gov/25478197/.*

D.10 Appropriate Treatment for Upper Respiratory Infection (URI)

Category	Description
CBE # / eCQM CBE #:	0069 / N/A
Quality #:	065
CMS eCQM ID:	CMS154v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.
Substantive Change:	**Updated denominator exclusion: For all collection types: Revised:** Exclude URI episodes where the patient is taking antibiotics in the 30 days prior to the episode date. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for malignant neoplasms to the "Comorbid Conditions for Respiratory Conditions" value set, and aggressive periodontitis to the "Competing Conditions for Respiratory Conditions" value set. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Outpatient visits, telephone visits, online assessments (i.e. e-visit or virtual check-in), observation stays or emergency department visits with a diagnosis of upper respiratory infection (URI) from January 1 to December 28 for patients 3 months of age and older. **Updated denominator instructions: For the MIPS CQMs Specifications collection type: Added:** An episode is defined as each eligible encounter for patients aged 3 months of age and older with a diagnosis of upper respiratory infection during the measurement period of January 1 to December 28. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion: **Added:** Aminoglycosides: Amikacin, Gentamicin, Streptomycin, Tobramycin To Beta-lactamase inhibitors: Ampicillin-sulbactam, Piperacillin-tazobactam Fourth-generation cephalosporins: Cefepime To Lincomycin derivatives: Lincomycin Miscellaneous antibiotics: Aztreonam, Chloramphenicol, Dalfopristin-quinupristin, Daptomycin, Linezolid, Metronidazole, Vancomycin To Natural penicillins: Penicillin G benzathine, Penicillin G benzathine procaine, Penicillin G procaine To Penicillinase-resistant penicillins: Nafcillin, Oxacillin To Quinolones: Gemifloxacin Rifamycin derivatives: Rifampin To Second generation cephalosporins: Cefotetan, Cefoxitin To Sulfonamides: Sulfadiazine To Third generation cephalosporins: Cefotaxime, Ceftazidime Urinary anti-infectives: Fosfomycin, Nitrofurantoin, Nitrofuantoin macrocrystals-monohydrate, Trimethoprim **Removed:** Folate antagonist From Macrolides: Erythromycin ethylsuccinate, Erythromycin lactobionate, Erythromycin stearate From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion for all collection types to exclude patients who were actively taking antibiotics in the 30 days prior to the encounter. We propose to remove the clause of actively taking antibiotics on the day of the encounter as the measure logic does not check for antibiotic use of the day of the encounter. The revised denominator exclusion would align the measure logic across antibiotic measures and ensure the appropriate patient population is being assessed for antibiotics prescribed on the date of the encounter. We propose to update the value set/coding for the eCQM Specifications collection type by adding coding for 'Aggressive periodontitis' to the "Competing Conditions for Respiratory Conditions (2.16.840.1.113883.3.464.1003.102.12.1017)" value set and coding for 'Neoplasms' to the "Comorbid Conditions for Respiratory Conditions ((2.16.840.1.113883.3.464.1003.102.12.1017)" value set, which would allow clinicians to use the denominator exclusion as it may be appropriate to dispense antibiotics to these patients. Additionally, it would create alignment with NCQA's HEDIS measure. We propose to update the denominator and denominator instructions for the MIPS CQMs Specifications collection type to revise the timeframe for eligible encounters as this would align with the numerator timeframe of 'on or within 3 days of the eligible encounter'. We propose to update the list of antibiotic medications for purposes of determining patients appropriate for the denominator exclusion for the MIPS CQMs Specifications collection type by adding and removing prescriptions to align with the current medication table to ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is applicable.

D.11 Appropriate Testing for Pharyngitis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	066
CMS eCQM ID:	CMS146v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.
Substantive Change:	**Updated denominator exclusion: For all collection types: Revised:** Exclude URI episodes where the patient is taking antibiotics in the 30 days prior to the episode date. **Updated value set/coding: For the eCQM Specifications collection type: Added:** coding for malignant neoplasms to the 'Competing Conditions for Respiratory Conditions' value set. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Outpatient, telephone, online assessment (i.e. e-visit or virtual check-in), observation, or emergency department (ED) visits with a diagnosis of pharyngitis or tonsilitis from January 1 to December 28 and an antibiotic order on or within 3 days after the episode date among patients 3 years or older. **Updated denominator instructions: For the MIPS CQMs Specifications collection type: Revised:** An episode is defined as each eligible encounter for patients aged 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order during the measurement period of January 1 to December 28. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion: **Removed:** From macrolides: Erythromycin ethylsuccinate, Erythromycin lactobionate, Erythromycin stearate Penicillinase resistant penicillins From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion for all collection types to exclude patients who were actively taking antibiotics in the 30 days prior to the encounter. We propose removal of the clause of actively taking antibiotics on the day of the encounter as the measure logic does not check for antibiotic use of the day of the encounter. The revised denominator exclusion would align the measure logic across antibiotic measures and ensure the appropriate patient population is being assessed for antibiotics prescribed on the date of the encounter. We propose to update the value set/coding for the eCQM Specifications collection type by adding coding for malignant neoplasms to the "Competing Conditions for Respiratory Conditions (2.16.840.1.113883.3.464.1003.102.12.1025)" value set which would allow clinicians to use the denominator exclusion as it may be appropriate to dispense antibiotics to these patients. Additionally, it creates alignment with NCQA's HEDIS measure. We propose to update the denominator and denominator instructions for the MIPS CQMs Specifications collection type to revise the timeframe for eligible encounters as this would align with the numerator timeframe of 'through 3 days after the eligible encounter'. We propose to update the list of antibiotic medications for purposes of determining patients appropriate for the denominator exclusion for the MIPS CQMs Specifications collection type by adding and removing prescriptions to align with the current medication table to ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is applicable.

D.12 Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	104
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.
Substantive Change:	**The denominator definition is revised to read:** **Risk Strata – Very Low, Low, Intermediate, High, or Very High –** **Very Low Risk** – PSA < 10 ng/mL; AND Gleason score 6 or less/Gleason grade group 1; AND clinical stage T1c; AND presence of disease in fewer than 3 biopsy cores; AND ≤ 50% prostate cancer involvement in each fragment/core; AND PSA density < 0.15 ng/mL/g. **Low Risk** – PSA < 10 ng/mL; AND Gleason score 6 or less/Gleason grade group 1; AND clinical stage T1 to T2a. **Intermediate Risk** – PSA 10 to 20 ng/mL; OR Gleason score 7/Gleason grade group 2-3; OR clinical stage T2b to T2c; AND no high-risk group or very-high-risk group features. **High Risk** – Has one of the following: PSA > 20 ng/mL; OR Gleason score 8 to 10/Gleason grade group 4-5; OR clinically localized stage T3a, without any very-high-risk group features. **Very High Risk** – At least one of the following: Clinical stage T3b to T4; OR primary Gleason pattern 5; OR more than 4 cores with Gleason score 8 to 10/Gleason grade group 4-5 OR 2-3 high-risk features. (NCCN, 2022) **External beam radiotherapy** – "External beam radiotherapy" refers to 3D conformal radiation therapy (3D- CRT), intensity modulated radiation therapy (IMRT), stereotactic body radiotherapy (SBRT), and proton beam therapy.
Measure Steward:	American Urological Association Education and Research
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator definition to better classify risk category for patients receiving treatment for prostate cancer in accordance with revised NCCN guidelines.[443]

[443] Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline, Part I: Introduction, Risk Assessment, Staging, and Risk-Based Management. The Journal of Urology, 208(1), 10–18. *https://doi.org/10.1097/JU.0000000000002757.*

Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline, Part II: Principles of Active Surveillance, Principles of Surgery, and Follow-Up. The Journal of Urology, 208(1), 19–25. *https://pubmed.ncbi.nlm.nih.gov/35536148/.*

Eastham, J. A., Auffenberg, G. B., Barocas, D. A., Chou, R., Crispino, T., Davis, J. W., Eggener, S., Horwitz, E. M., Kane, C. J., Kirkby, E., Lin, D. W., McBride, S. M., Morgans, A. K., Pierorazio, P. M., Rodrigues, G., Wong, W. W., & Boorjian, S. A. (2022). Clinically Localized Prostate Cancer: AUA/ASTRO Guideline. Part III: Principles of Radiation and Future Directions. The Journal of Urology, 208(1), 26–33. *https://pubmed.ncbi.nlm.nih.gov/35536141/.*

D.13 Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis

Category	Description
CBE # / eCQM CBE #:	0058 / N/A
Quality #:	116
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) services. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Table 1 – Antibiotic medications to be utilized for the denominator exclusion and numerator components: **Removed:** Ketolides From Third generation cephalosporins: Ceftibuten, Cefditoren
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator criteria to include coding for FQHC services to standardize codes in the value sets and align with the HEDIS version of this measure (*https://www.ncqa.org/hedis/measures/avoidance-of-antibiotic-treatment-for-acute-bronchitis-bronchiolitis/*). We propose to update the list of antibiotic medications, found in Table 1 – Antibiotic Medications, used to determine patients who are appropriate for the denominator exclusion and numerator compliance. This proposed update would ensure the appropriate patient population is being identified for denominator eligibility and ensuring the quality action is assessed appropriately by removing antibiotics that may not fully align with the measure intent and standardizing medication names to maintain alignment with the HEDIS measure.

D.14 Diabetes: Eye Exam

Category	Description
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Updated denominator exclusion: For the** MIPS CQMs Specifications collection type**: Added:** Dementia combinations: Donepezil-memantine **to** list of dementia exclusion medications. **Updated numerator note: For the MIPS CQMs Specifications collection type: Added:** reporting of CPT 92229 meets the intent of the quality action for performance met.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion for the MIPS CQMs Specifications collection type to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. Additionally for the MIPS CQMs Specifications collection type, we propose to update the numerator note to indicate that denominator eligible patients who receive services under CPT code 92229 would meet the intent of the measure and should be included in the appropriate performance met numerator option, based on retinopathy findings.

D.15 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)

Category	Description
CBE # / eCQM CBE #:	0066 / N/A
Quality #:	118
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.
Substantive Change:	**Updated denominator criteria: Removed:** For all submission criteria: coding for subsequent myocardial infarction. **Updated denominator exception: Removed:** For all submission criteria: other reasons attributable to the health care system.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove patients with subsequent MI from the denominator criteria as this patient population is duplicative in nature. For the purposes of this measure, those patients with a subsequent MI would already have a diagnosis of CAD from the initial MI. Therefore, these patients would already be correctly included in the denominator eligible patient population. We propose to remove documentation of system reason(s) from the denominator exception as this option is not recommended for this measure due to wide-spread availability of these medications. This would also create alignment within the denominator exceptions across all AHA measures.

D.16 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	134
CMS eCQM ID:	CMS2v13
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **Updated guidance: For the eCQM Specifications collection type: Revised:** The intent of the measure is to screen for new cases of depression in patients who have never had a diagnosis of bipolar disorder. Patients who have ever been diagnosed with bipolar disorder prior to the qualifying encounter used to evaluate the **numerator** will be excluded from the measure regardless of whether the diagnosis is active or not. **Updated denominator exclusion: For all collection types: Removed:** Diagnosis of depression from the denominator exclusion. **Updated denominator note: For the** MIPS CQMs Specifications **and Medicare Part B Claims Specifications collection types: Removed:** Diagnosis of depression from the denominator note. **Updated denominator definition: For the MIPS CQMs Specifications and Medicare Part B Claims Specifications collection types: Removed:** Diagnosis of depression from the denominator exclusion definition. **Updated denominator criteria: For all collection types: Added:** coding for qualifying encounters for nutritionists/dieticians and home-based health care.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We propose to revise the guidance for the eCQM Specifications collection type to reflect inclusion of patients with a previous inactive (or resolved) diagnosis of depression as it is important to identify patients who have been treated for depression in the past but may have re-emerging symptoms. We also propose to revise the denominator exclusion to remove a diagnosis of depression as an applicable exclusion, as patients with a history of depression may require more frequent monitoring and ongoing treatment for reoccurrence of symptoms. We propose to update the denominator to include encounter codes for nutritionists and dieticians, as well as home-based encounter codes, as it is clinically appropriate to conduct depression screenings during these encounters.

D.17 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care

Category	Description
CBE # / eCQM CBE #:	0563 / N/A
Quality #:	141
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12 month performance period.
Substantive Change:	**The measure title is revised from 'Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care ' to:** Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care. **The measure description is revised to read: For all collection types:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period. **The measure numertor is revised to read: For all collection types:** Patients whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period. **Updated definitions: For all collection types: Revised: Glaucoma Treatment Not Failed** – The most recent IOP was reduced by at least 20% in the affected eye or if both eyes were affected, the reduction of at least 20% occurred in both eyes from pre-intervention levels. **Updated numerator instructions: For all collection types: Revised:** to reflect an IOP reduction goal of 20% or more from pre-intervention levels. **Updated numerator options: For all collection types: Revised:** to reflect an IOP reduction goal of 20% or more from pre-intervention levels.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise multiple components of this measure for all collection types to align with the latest scientific evidence that shows that 20 percent reduction in pre-intervention IOP optimizes patient outcomes by reducing the rate of worsening visual fields and is used as a benchmark for treatment outcomes. In a recent randomized clinical trial comparing phaco/Kahook Dual Blade to phaco/iStent, success was defined as at least a 20 percent reduction in IOP or reduction of one or more glaucoma medications from baseline.[444] In the only multicenter randomized clinical trial comparing minimally invasive glaucoma surgery standalone procedures, the COMPARE Study defined success as an unmedicated IOP reduction of at least 20 percent from baseline or unmedicated IOP less than or equal to 18 mmHg.[445]

[444] Falkenberry, S., Singh, I. P., Crane, C. J., Haider, M. A., Morgan, M. G., Grenier, C. P., ... & Dorairaj, S. (2020). Excisional Goniotomy vs. Trabecular Microbypass Stent Implantation: A Prospective Randomized Clinical Trial in Eyes with Mild to Moderate Open-Angle Glaucoma. Journal of Cataract & Refractive Surgery, 46(8), 1165-1171. *https://doi.org/10.1097/j.jcrs.0000000000000229.*

[445] Ahmed, I. I. K., Fea, A., Au, L., Ang, R. E., Harasymowycz, P., Jampel, H. D., ... & COMPARE Investigators. (2020). A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma: The COMPARE Study. *Ophthalmology*, *127*(1), 52-61. *https://www.amedeolucente.it/public/A%20Prospective%20Randomized%20Trial%20Comparing.pdf.*

D.18 Functional Outcome Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	182
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.
Substantive Change:	**Updated numerator definition: Revised:** Functional Outcome Deficiencies – Impairment, loss of function, or difficulty with participation in daily activities related to physical (e.g., musculoskeletal, cardiovascular, pulmonary, integumentary), sensory, cognitive, behavioral, or visual/perceptual impairments. **Updated denominator criteria: Added:** coding for cognitive assessment.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the numerator definition to describe assessment areas more accurately and completely for physical therapy and occupational therapy clinicians. We also propose to add qualifying encounter coding utilized for cognitive assessment, as the quality action would be appropriate for this patient population.

D.19 Stroke and Stroke Rehabilitation: Thrombolytic Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	187
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.
Substantive Change:	**Updated denominator exception: Removed:** Tenecteplase (TNK) as an example of a denominator exception.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove Tenecteplase (TNK) as one of the examples for the denominator exception as the numerator action is looking at patients for whom IV thrombolytic therapy was initiated within 4.5 hours.

D.20 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
CBE # / eCQM CBE #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic to ensure surgeries on Sep 30 are included in the denominator.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the measure logic for the eCQM Specifications collection type to include cataract surgeries performed on September 30 to align with the measure intent of including all cataract surgeries performed between January 1st and September 30th of the measurement period.

D.21 HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	205
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **The measure description is revised to read:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period. **Updated instructions: Removed:** Only patients who had at least two visits during the performance period, with at least 90 days between each visit will be counted in the denominator for this measure. **The denominator is revised to read:** All patients 13 years of age and older at the start of the performance period with a diagnosis of HIV before the end of the performance period with an eligible encounter during the performance period. **Updated denominator criteria: Revised:** age determined at start of the performance period. **Removed:** At Least Two Denominator Eligible Encounters During the Measurement Year, With at Least 90 days Between Each. **Added:** coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, residence services, and preventive medicine. **Updated denominator exclusion: Removed:** exclusion for patients receiving hospice services. **The numerator is revised to read:** Patients who were tested for each of the following at least once during the performance period: syphilis, gonorrhea, and chlamydia. **Updated denominator exception: Removed:** Chlamydia, gonorrhea, and syphilis screening results not documented (Patient refusal is the only allowed exception).
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the collection types available for this measure to include the eCQM Specification collection type to allow choice in submission method. We propose to update the measure to reflect the clinical recommendations[446] [447] for annual sexually transmitted infections (STIs) screenings given the prevalence of sexually transmitted co-infections over the course of HIV disease. According to one literature review, the mean prevalence of STI co-infection was 16.3 percent with syphilis, gonorrhea, and chlamydia showing median rates of 9.5 percent, 9.5 percent, and 5 percent respectively.[448] A key takeaway from this review, continued high rates of co-occurring STIs in this patient population will hinder efforts in HIV transmission prevention. We propose to update the instructions and denominator criteria to remove the requirement for at least two denominator eligible visits to ensure all patients who have been diagnosed with HIV receive appropriate testing. We propose to revise the age anchor to be at the start of the performance period to reduce burden in implementation and add coding for preventive medicine encounters, nonphysician, physician, and qualified health care professional (QHP) telephone assessments, and home or residence visits as it would be appropriate for patients at these encounters to be assessed for the quality action. We propose to remove the denominator exclusion for patients who use hospice services as it may still be appropriate to screen for and subsequently treat these infections. Additionally, we propose to remove the denominator exception for patient refusal as these sexually transmitted diseases can increase the risk for HIV infection through increases in the infectiousness and an individual's susceptibility.[449]

[446] US Preventive Services Task Force, Mangione, C. M., Barry, M. J., Nicholson, W. K., Cabana, M., Chelmow, D., Coker, T. R., Davis, E. M., Donahue, K. E., Jaén, C. R., Kubik, M., Li, L., Ogedegbe, G., Pbert, L., Ruiz, J. M., Stevermer, J., & Wong, J. B. (2022). Screening for Syphilis Infection in Nonpregnant Adolescents and Adults: US Preventive Services Task Force Reaffirmation Recommendation Statement. *JAMA, 328*(12), 1243–1249. *https://doi.org/10.1001/jama.2022.15322.*

[447] US Preventive Services Task Force, Davidson, K. W., Barry, M. J., Mangione, C. M., Cabana, M., Caughey, A. B., Davis, E. M., Donahue, K. E., Doubeni, C. A., Krist, A. H., Kubik, M., Li, L., Ogedegbe, G., Pbert, L., Silverstein, M., Simon, M. A., Stevermer, J., Tseng, C. W., & Wong, J. B. (2021). Screening for Chlamydia and Gonorrhea: US Preventive Services Task Force Recommendation Statement. *JAMA, 326*(10), 949–956. *https://doi.org/10.1001/jama.2021.14081.*

[448] Kalichman, S. C., Pellowski, J., & Turner, C. (2011). Prevalence of Sexually Transmitted Co-infections in People Living with HIV/AIDS: Systematic Review with Implications for Using HIV Treatments for Prevention. *Sexually Transmitted Infections, 87*(3), 183–190. *https://doi.org/10.1136/sti.2010.047514.*

[449] Hayes, R. J., Watson-Jones, D., Celum, C., van de Wijgert, J., & Wasserheit, J. (2010). Treatment of Sexually Transmitted Infections for HIV Prevention: End of the Road or New Beginning? *AIDS (London, England), 24*(0 4), S15–S26. *https://doi.org/10.1097/01.aids.0000390704.35642.47.*

D.22 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	226
CMS eCQM ID:	CMS138v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.
Substantive Change:	**Updated measure description: For all collection types: Revised:** Patient age to 12 years and older. **Updated instructions: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 12 years and older. 1) **Updated initial patient population: For the eCQM Specifications Collection type: Revised:** All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period. **Updated denominator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For all submission criteria: Patient age to 12 years and older. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** For all submission criteria: Patient age to 12 years and older. **Updated measure analytic: For all collection types: Revised:** data completeness will be determined utilizing performance rate one.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure for all collection types to combine the patient population within Q402: Tobacco Use and Help with Quitting Among Adolescents with that of Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention resulting in a single, more robust measure, by lowering the denominator eligible age to 12 years and older to allow for the inclusion of adolescents into the measure's denominator. Measure Q402 has been proposed for removal under Table C.11 of this Appendix. We propose to update the analytic of the measure to utilize performance rate one for the determination of data completeness to ensure a complete data set is submitted and inclusive of all denominator eligible patients for this measure. As submission criteria two only includes those patients identified as tobacco users, the intent of the measure is to also ensure screening of all patients aged 12 years and older. Assessing data completeness utilizing submission criteria one will ensure that screening information was collected.

D.23 Controlling High Blood Pressure

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	236
CMS eCQM ID:	CMS165v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare CQMs Specifications, Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications collection type. **The measure guidance is revised to read: For the eCQM Specifications collection type:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **The measure instructions note and numerator note are revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications. **The measure initial patient population is revised to read: For the eCQM Specifications collection type:** Patients 18-85 years of age by the end of the measurement period who had a visit during the measurement period and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the collection types available for this measure to include the Medicare CQMs Specifications collection type to allow choice in submission method for SSP ACOs reporting via the APP. See section IV.A.4.f.(1)(b) and section III.G.2. for further information on the Medicare CQMs Specifications collection type. We propose to revise the initial patient population for the eCQM Specifications collection type by specifying the patient visit must occur during the measurement period to clarify the encounter timing. We propose to revise the measure guidance for the eCQM Specifications collection type and the instructions note and numerator note for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types around remote monitoring devices for capturing blood pressure readings. Currently, the measure allows patient reported data using most methods of digital collection/reporting and prohibits patient reported data taken with non-digital devices, such as with a manual blood pressure cuff and stethoscope. The measure is agnostic to how the reading gets in and the documentation practice of each office; therefore, whether patient is "conveying the reading to the clinician" by manually entering the BP reading (for example, patient portal) or having the device auto-transmit data directly, it is the clinician's responsibility and discretion to confirm that the automated blood pressure monitor used to obtain the blood pressure is considered acceptable and reliable. Additionally, we propose to update the denominator exclusion for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.

D.24 Use of High-Risk Medications in Older Adults

Category	Description
CBE # / eCQM CBE #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.
Substantive Change:	**Updated numerator definition: For the MIPS CQMs Specifications collection type: Revised:** For Numerator (Submission Criteria 1): Definitions: Table 1 - High-Risk Medications at any dose or duration:

Category	Description
	Revised: Antithrombotics – Dipyridamole (oral, excluding extended release) Cardiovascular, other – Nifedipine (excluding extended release) Table 2 - High-Risk Medications With Days Supply Criteria **Removed:** From Anti-Infectives, other - Nitrofurantoin macrocrystals Table 3 - High-Risk Medications With Average Daily Dose Criteria **Added:** Description: Alpha agonists, central Description: Cardiovascular, other Description: Tertiary tricyclic antidepressants (TCAs) (as single agent or as part of combination products) **Removed:** Doxepin hydrochloride For Numerator (Submission Criteria 2): Definitions: Table 4 - High-Risk Medications **Added:** To Antipsychotics, first (conventional) and second (atypical) generation - Aripiprazole lauroxil **The measure numerator is revised to read: For the eCQM Specifications collection type:** Submission Criteria/Rate 2: Patients with at least two orders of high-risk medications from the same drug class (i.e., antipsychotics and benzodiazepines) on different days except for appropriate diagnoses. a. Patients with two or more antipsychotic prescriptions ordered on different days, and who did not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the IPSD for antipsychotics. b. Patients with two or more benzodiazepine prescriptions ordered on different days, and who did not have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated numerator exclusion: For the eCQM Specifications collection type: Removed:** Rate 2: For patients with two or more antipsychotic prescriptions ordered on different days, and who did not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the IPSD for antipsychotics. For patients with two or more benzodiazepine prescriptions ordered on different days, and who did not have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated numerator logic: For the eCQM Specifications collection type: Revised:** for medications ordered on the same day intended to start on different dates.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the medication tables for the MIPS CQMs Specifications collection type to align with the current guidelines and ensure appropriate high-risk medications are identified. This would align with the intent of the measure and ensure the appropriate patient population is being assessed for the quality action. We propose to update the numerator for all collection types to clarify and ensure capture of the appropriate patient population. For the eCQM Specifications collection type, this was achieved by removing the standalone numerator exclusion and incorporating the exclusion language in the numerator criteria, to mitigate previous implementation concerns. Additionally, we propose to add logic for medications ordered on the same day but intended to start on different dates.

D.25 Childhood Immunization Status

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	240
CMS eCQM ID:	CMS117v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three Hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one Hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.
Substantive Change:	**Updated numerator: Revised:** IPV, MMR, VZV, PCV, Hep A, and Flu: to allow for anaphylaxis due to the vaccine to count towards numerator compliance.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add language excluding patients with anaphylaxis due to vaccine administration to 6 of the 10 numerator criteria where applicable. A history of a severe allergic reaction to a vaccine should be considered a contraindication to additional doses of the same vaccine *(https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html).*

D.26 Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
CBE # / eCQM CBE #:	0643 / N/A
Quality #:	243
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.
Substantive Change:	**Updated denominator criteria: Removed:** From 'Coronary Artery Bypass Graft Surgery' coding for endoscopic procedures on the heart and pericardium.
Measure Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove coding for endoscopic procedures of the heart and pericardium as the coding is more related to the harvest of the artery and not the cardiac surgery itself and therefore, these patients may not be appropriate for the quality action.

D.27 Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	254
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.
Substantive Change:	**Updated denominator criteria:** **Revised:** Diagnosis of Other Current Condition in the Mother Classifiable Elsewhere but Complicating Pregnancy, Childbirth, or the Puerperium to Current Diagnosis of Pregnancy. **Added:** coding for other and unspecified abnormal uterine and vaginal bleeding and current diagnosis of pregnancy. **Updated denominator exception: Removed:** patient has visited the ED multiple times within 72 hours. **Updated measure instructions and numerator instructions: Revised: submission** frequency **from each time to each visit.**
Measure Steward:	American College of Emergency Physicians
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator criteria to include other and unspecified abnormal uterine and vaginal bleeding coding and revised the criteria for pregnancy to ensure all applicable patients are being included in the denominator eligible population and are being appropriately assessed. Additionally, we propose to remove the exception for those patients that have visited the ED multiple times within 72 hours and revise the measure submission to each denominator eligible visit as it would be clinically appropriate for them to receive an ultrasound with pregnancy location determination at each visit.

D.28 Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	275
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.
Substantive Change:	**The measure denominator is revised to read:** All patients, regardless of age, with a diagnosis of inflammatory bowel disease who initiated an anti-TNF agent during the performance period. **Updated denominator definition: Revised:** initiated an anti-TNF agent. **Updated denominator criteria: Revised:** initiated an anti-TNF agent.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add initiated an anti-TNF agent during the performance period in order to capture the intended patient population accurately. As the measure is currently written, it would allow patients who initiated treatment prior to the performance period and could inflate the intended population and possibly impact performance negatively with no clinician recourse.

D.29 Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	279
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.
Substantive Change:	**The measure title is revised from 'Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy' to:** Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy. **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available). **The measure denominator is revised to read:** All patients aged 18 years and older with obstructive sleep apnea who were prescribed an evidence-based therapy. **Updated denominator definition: Added:** Evidence-based Therapy – includes positive airway pressure, oral appliances, positional therapies, hypoglossal nerve stimulation, or other devices with monitoring capabilities. **Updated denominator criteria: Revised:** coding to reflect a diagnosis of obstructive sleep apnea. **Revised:** Evidence-based therapy was prescribed. **Updated numerator: Revised:** Patients with documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available). **Updated numerator definition: Added:** Documentation of adherence to therapy – includes a note documented in the patient's medical record that patient is adherent to the prescribed therapy for obstructive sleep apnea. Objective Informatics – a telemonitoring system that shows data demonstrating patient adherence to the prescribed therapy for obstructive sleep apnea (i.e., CPAP machines with SD cards that store data). Self-Reporting – patient and/or parent/caregiver attests to compliance with prescribed therapy for obstructive sleep apnea, which is documented in the medical record. Objective Reporting – data that are reported from an objective informatics or other data source and is not reported by the patient or parent/caregiver. **Removed:** Objectively Measured definition. **Updated numerator options: Revised:** Performance Met: Adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available, documented) Denominator Exception: Documentation of reason(s) for not objectively reporting adherence to evidence-based therapy (e.g., patients who have been diagnosed with a terminal or advanced disease with an expected life span of less than 6 months, patients who decline therapy, patients who do not return for follow-up at least annually, patients unable to access/afford therapy, patient's insurance will not cover therapy) Performance Not Met: Adherence to therapy was not assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available), reason not given.
Measure Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update multiple components of this measure to reflect on the assessment of patients with obstructive sleep apnea (OSA) who were prescribed an evidence-based therapy by revising the denominator criteria to reflect this patient population. We propose revisions to this measure to add flexibility in how the numerator is evaluated by allowing self-reporting for patients who don't have access to objective informatics systems or where resources may not be available. Additionally, we propose to add definitions that would clarify the intended denominator eligible patient population and appropriate clinical action for numerator compliance.

D.30 Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	291
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and occupational therapy clinician types.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add additional coding for speech language pathology and occupational therapy encounters. This would ensure a more complete denominator patient population is captured as it would be clinically appropriate for these clinician types to complete the quality action.

D.31 Chlamydia Screening for Women

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	310
CMS eCQM ID:	CMS153v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.
Substantive Change:	**Updated denominator exclusion: Revised:** Women who are only eligible for the initial population due to a pregnancy test during the measurement period, and who had an order for an x-ray or for a specified medication on the date of the pregnancy test or the six days after the pregnancy test.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion language to clarify the timing. The original measure language "within 7 days" is ambiguous as it can be interpreted as either "7 days after pregnancy test" or "on the day of pregnancy test and 6 days after". Therefore, clarifying the timeframe within the measure to evaluate a 7-day period better aligns with the measure intent of to include the day of the pregnancy test.

D.32 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	317
CMS eCQM ID:	CMS22v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated denominator: For all collection types: Added:** coding for audiology.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator criteria for all collection types to include audiology codes within the denominator eligible encounter criteria as this measure is applicable to their scope of care. Patients with high blood pressure are at an increased risk of hearing loss as compared to those without hypertension, making this concept important for audiologists to assess.[450]

[450] Agarwal, S., Mishra, A., Jagade, M., Kasbekar, V., & Nagle, S. K. (2013). Effects of Hypertension on Hearing. Indian Journal of Otolaryngology and Head and Neck Surgery: Official Publication of the Association of Otolaryngologists of India, 65(Suppl 3), 614–618. *https://doi.org/10.1007/s12070-013-0630-1.*

D.33 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	326
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator exception: Revised:** Documentation of medical reason(s) for not prescribing an FDA-approved anticoagulant (e.g., present or planned atrial appendage occlusion or ligation or patient being currently enrolled in a clinical trial related to AF/atrial flutter treatment) **Removed:** documentation of system reasons exception.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exception to include patients currently being enrolled in a clinical trial related to AF/atrial flutter treatment as a medical reason for exception. Patients that are enrolled into a clinical trial related to AF/atrial flutter treatment may have contraindications for receiving FDA-approved oral anticoagulant drug therapy. Additionally, we propose to remove the denominator exception for documentation of system reason(s) as this option is not recommended for this measure due to wide-spread availability of these medications. This would also create alignment within the denominator exceptions across all American Heart Association (AHA) measures.

D.34 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	331
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.
Substantive Change:	**Updated instructions: Added:** Each unique occurrence is defined as a 90-day period from onset of acute viral sinusitis symptoms. If multiple occurrences are documented within a 90-day period, Merit-based Incentive Payment System (MIPS) eligible clinicians should submit the most recent instance.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure instructions to include additional clarifying language to remove ambiguity related to the definition of an occurrence of acute viral sinusitis. The revisions define a unique occurrence of acute viral sinusitis as a 90-day period from onset of acute viral sinusitis and include guidance in instances where multiple occurrences are documented.

D.35 HIV Viral Load Suppression

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	338
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications collection type. **Updated instructions: Revised:** timing for patient encounter to the first 240 days of the performance period. **The measure description is revised to read:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period. **The measure denominator is revised to read:** All patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period with at least one eligible encounter in the first 240 days of the performance period. **Updated denominator criteria: Added:** coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, residence services, and preventive medicine. Revised: timing for HIV diagnosis to be prior to or during the first 90 days of the performance period. Revised: timing for the denominator eligible encounter to occur during the first 240 days of the performance period.
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the collection types available for this measure to include the eCQM Specification collection type to allow choice in submission method. We propose to revise the measure description and denominator to update the timing of the patient's HIV diagnosis and eligible encounter. Requiring the HIV diagnosis before or with the first 3 months of the performance period in conjunction with limiting the eligible encounter timeframe allows the MIPS eligible clinician time to treat the patient in an effort to achieve numerator compliance. A viral load less than 200 copies/mL is optimal for patients with HIV to stay healthy and reduce transmission to others (*https://www.cdc.gov/hiv/risk/art/index.html*). According to the Panel on Antiretroviral Guidelines for Adults and Adolescents, antiretroviral therapy (ART) should be initiated as soon as possible after HIV diagnosis (*https://www.ncbi.nlm.nih.gov/books/NBK586306/*). Furthermore, the Panel on Antiretroviral Guidelines for Adults and Adolescents states indicates that individuals who are adherent to their ARV regimen and do not harbor resistance mutations to the component drugs can generally achieve suppression 8 to 24 weeks after ART initiation; rarely, in some patients it may take longer. Additionally, we propose to update the measure to include coding for telephone assessments with nonphysician/QHPs, residence services, and preventive medicine visits within the denominator eligible encounter criteria as this measure is applicable to the scope of care given by these clinicians.

D.36 Follow-Up Care for Children Prescribed ADHD Medication (ADD)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	366
CMS eCQM ID:	CMS136v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.
Substantive Change:	**Updated definition: Added:** Treatment days (covered days): The actual number of calendar days covered with prescriptions during the 301-day period. Use the following steps to identify and calculate covered days. Step 1: For same medications that are prescribed on the same day or on different days with overlapping days' supply, the days' supply is summed. The start and end dates are then identified. The start date is the date of service of the earliest prescription event and the first covered day. The end date is the calendar day when the days' supply runs out. The start date through the end date are considered covered days. This rule assumes that the patient will take one prescription at a time (and start taking the next prescription after exhausting the previous prescription). For example: - If there are three 7-days' supply prescription events for the same medication on January 1, the start date is January 1 and the end date is January 21. Covered days include January 1–21. - If there are two 7-days' supply prescription events for the same medication on January 1 and January 5, the start date is January 1 and the end date is January 14. Covered days include January 1–14. - If there are three 7-days' supply prescription events for the same medication on January 1, a 7-days' supply prescription event on January 20 and a 7-days' supply prescription event on January 28, the start date is January 1 and the end date is February 4. Covered days include January 1–February 4. Step 2: For all other events (multiple prescriptions for the same medication on different days without overlap, multiple prescriptions for different medications on the same or different days, with or without overlap), the covered days are identified by the start and end dates for each prescription event individually. The start date through the end date are considered covered days. This rule assumes the member will take the different medications concurrently. Step 3: Each calendar day covered by one or more medications is considered one covered day. **The initial patient population is revised to read:** Initial Population 1: Children 6-12 years of age as of the Intake Period who had an IPSD and who had a visit within 6 months prior to the IPSD including the IPSD. Children are removed if they had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Initiation Phase. Initial Population 2: Children 6-12 years of age as of the Intake Period who had an IPSD and remained on the medication for at least 210 treatment days during the 301-day period, beginning on the IPSD through 300 days after the IPSD, and who had a visit within 6 months prior to the IPSD including the IPSD. Children are removed if they had an acute inpatient stay with a principal diagnosis of mental, behavioral or neurodevelopmental disorder during the Continuation and Maintenance Phase. **The measure numerator is revised to read:** Numerator 2: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase, and at least two follow-up visits on different dates of service during the 31-300 days after the IPSD.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing revisions to this measure that would simplify the logic and create definitions to align with the HEDIS measure by identifying the index prescription start date (IPSD) with negative medication history. We also propose to change the denominator qualifying encounter timeframe from during the measurement year to 6 months prior to the IPSD, which would enable the measure to attribute patients to clinicians who have a greater chance of interacting with the patient and/or prescribing the medication. Additionally, we propose to revise the numerator to align with the measure intent by clarifying that the two follow-up visits must occur on different dates.

D.37 Depression Remission at Twelve Months

Category	Description
CBE # / eCQM CBE #:	0710 / 0710e
Quality #:	370
CMS eCQM ID:	CMS159v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** Exclusion for patients who were permanent nursing home residents during the denominator identification period or the measure assessment period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update all collection types to remove the denominator exclusion related to patients who were permanent nursing home residents. This component has an extremely low rate of use, demonstrating that it's not a meaningful exclusion for the measure.

D.38 Functional Status Assessment for Total Hip Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	376
CMS eCQM ID:	CMS56v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270 – 365 days after the surgery.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery. **The measure denominator exclusions are revised to read:** 1. Exclude patients who are in hospice care for any part of the measurement period. Exclude patients with severe cognitive impairment that starts before or in any part of the measurement period. 1. Exclude patients with one or more specific lower body fractures indicating trauma in the 24 hours before or at the start of the total hip arthroplasty. 2. Exclude patients with a partial hip arthroplasty procedure on the day of the total hip arthroplasty. 3. Exclude patients with a revision hip arthroplasty procedure, an implanted device/prosthesis removal procedure or a resurfacing/supplement procedure on the day of the total hip arthroplasty. 4. Exclude patients with a malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm on the day of the total hip arthroplasty. 5. Exclude patients with a mechanical complication on the day of the total hip arthroplasty. 6. Exclude patients with a second total hip arthroplasty procedure 1 year before or after the original total hip arthroplasty procedure. 7. Exclude patients who die on the day of the total hip arthroplasty procedure or in the 300 days after. **The initial patient population is revised to read:** Patients 19 years of age and older who had a primary THA between November two years prior to the measurement period and October of the year prior to measurement period; and who had an outpatient encounter between November of the year prior to the measurement period and the end of the measurement period. **Updated numerator: Revised:** timeframe for follow-up assessment to 300 – 425 days after the THA procedure.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to change the fracture exclusion from two fractures at the time of the procedure to one lower body fracture that would more accurately indicate a non-elective THA. We propose to add denominator exclusions to remove patients who do not receive elective THA and would not be appropriate for quality action assessment. We also propose to revise the initial patient population to push back the procedure timing and revise the numerator to extend the follow-up functional status assessment timing. This change harmonizes procedure and follow-up timing with other similar measures within the program reducing clinician burden when submitting similar measures across programs. This revision would also be reflected in the measure description.

D.39 Children Who Have Dental Decay or Cavities

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	378
CMS eCQM ID:	CMS75v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months to 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 1 – 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist. **The measure initial patient population is revised to read:** Children, 1 - 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the age range in the description and the initial patient population, as dental visits before age one aren't significantly related to first dental examinations (*https://pubmed.ncbi.nlm.nih.gov/25422016/*). This change creates alignment with measures across programs such as the Medicaid Child Core set dental measures and the Dental Quality Alliance measures.

D.40 Primary Caries Prevention Intervention as Offered by Dentists

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	379
CMS eCQM ID:	CMS74v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months to 20 years of age, who received a fluoride varnish application during the measurement period as determined by a dentist.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist. **Updated stratification: Revised:** Population 1 to reflect patient 1 – 5 years of age. **The measure initial patient population is revised to read:** Children, 1 – 20 years of age at the start of the measurement period, with a clinical oral evaluation by a dentist during the measurement period. **Updated numerator: Revised:** to require two fluoride varnishes on different days during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the age range for this measure as dental visits before age one are not significantly related to first dental examinations *(https://pubmed.ncbi.nlm.nih.gov/25422016/)*. This change creates alignment with measures across programs such as the Medicaid Child Core set dental measures and the Dental Quality Alliance measures. We also propose to update the numerator to require two fluoride applications within the measurement period as opposed to one fluoride application. This change would also align the measure with current evidence, clinical recommendations, and with the Topical Fluoride for Children measure used in the Medicaid Child Core Set as well as the Topical Fluoride for Children measure stewarded by the Dental Quality Alliance (*https://doi.org/10.14219/jada.archive.2013.0057*).

D.41 Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	382
CMS eCQM ID:	CMS177v12
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.
Substantive Change:	**The measure description is revised to read:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk. **The initial patient population is revised to read:** All patient visits for those patients aged 6 through 16 at the start of the measurement period with a diagnosis of major depressive disorder.
Measure Steward:	Mathematica
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description and initial patient population for the upper age limit to specify patients should be 16 years of age at the start of the measurement period. This would align with the current measure logic, which doesn't include patients who are 17 years of age.

D.42 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
CBE # / eCQM CBE #:	1879 / N/A
Quality #:	383
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator criteria: Added:** additional outpatient place of service coding. **Updated denominator exclusions: Revised:** to exclude patients who have ever had a diagnosis of dementia.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to add additional outpatient place of service coding for use with encounter coding for the outpatient, emergency department, and non-acute inpatient setting as schizophrenia may be diagnosed at encounters within these settings. This would ensure a complete denominator patient population is captured for quality action assessment. We also propose to expand the denominator exclusion so that it applies to patients who have ever had dementia as it is a chronic condition that can't be resolved and use of antipsychotics should be reserved for severe symptoms that have failed to respond adequately to nonpharmacological management strategies (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994396/*).

D.43 Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	386
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.
Substantive Change:	**The description is revised to read:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression). **The numerator is revised to read:** Patients who were offered assistance in planning for end of life issues or whose existing end of life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression). **Updated numerator options: Revised:** to include the concept of reviewing and updating an existing end of life plan.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the description, numerator, and numerator options to reflect numerator compliance for reviewing or updating an existing end of life plan. These revisions work to clarify the intent of the measure in regard to end of life issues and frequency, as well as the quality actions that would meet the intent of this measure, continuing to stress the importance of end of life planning.

D.44 Optimal Asthma Control

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	398
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.
Substantive Change:	**Updated denominator exclusion: Removed:** Patients who were permanent nursing home residents any time during the performance period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the measure criteria to remove patients who were permanent nursing home residents any time during the performance period from the denominator exclusions and allow these patients to be included within the denominator of this measure. Patients within a nursing home should still be assessed for the quality action within this measure as it supports overall health and quality of life.

D.45 One-Time Screening for Hepatitis C Virus (HCV) for all Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	400
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients age >= 18 years who received one-time screening for Hepatitis C Virus (HCV) infection.
Substantive Change:	**The measure title is revised from 'One-Time Screening for Hepatitis C Virus (HCV) for all patients' to:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation **The measure description is revised to read:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV **The measure instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients > =18 years AND who are seen twice for any visits or who have at least one preventive visit through September 30 of the performance period AND who have never received an HCV antibody test. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **This measure will be calculated with 2 performance rates:** 1. Percentage of patients age >= 18 years who have never been tested for HCV antibodies and who receive an HCV antibody test. 2. Percentage of patients age >= 18 years who have a reactive HCV antibody test, who have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. The denominator of submission criteria 2 is a subset of the resulting numerator for submission criteria 1, as submission criteria 2 is limited to assessing if patients who have a reactive HCV antibody test, have a follow up HCV viral test, and if HCV viremia is detected, treatment is initiated within three months or they are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. For all patients age >=18 years who have never been tested for HCV antibodies, submission criteria 1 is applicable, but submission criteria 2 will only be applicable for those patients who have a reactive HCV antibody test. A simple average, which is the sum of the performance rates divided by the number of the performance rates will be used to calculate performance. **NOTE:** Include only eligible encounters and HCV antibody test results documented through September 30 of the performance period. This will allow the evaluation of at least 90 days for treatment initiation or documentation of referral made within the performance period. **Updated denominator: Updated:** **THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE:** 1. All patients age >= 18 years age who have never been tested for HCV antibodies and who receive an HCV antibody test. AND 2. All patients age >= 18 years who have a reactive (positive) HCV antibody test and have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. This measure contains two submission criteria that aim to identify patients who are tested for HCV antibodies (submission criteria 1) and patients who have a reactive HCV antibody test and who have a follow up HCV viral test, and if HCV viremia is detected, have treatment initiated within three months or are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test (submission criteria 2). By separating this measure into various submission criteria, the MIPS eligible clinician will be able to better ascertain where gaps in performance exist and identify opportunities for improvement. For accountability reporting in the CMS MIPS program, the rate for submission criteria 2 is used for performance, however, both performance rates must be submitted. **Updated denominator/denominator criteria: Revised:** **SUBMISSION CRITERIA 1**: Patients who have never been tested for HCV antibodies and who receive an HCV antibody test. DENOMINATOR (Submission Criteria 1): All patients >= 18 years of age who are seen twice for any visits or who have at least one preventive visit January 1 and September 30 of the performance period. Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years of age **AND** At least one preventive encounter **OR** At least two patient encounters **AND NOT** **DENOMINATOR EXCLUSION:** Diagnosis for Chronic Hepatitis C OR

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	Documentation or patient report of HCV antibody test or HCV RNA test which occurred prior to the performance period. **Added:** **SUBMISSION CRITERIA 2:** Patients with a reactive (positive) HCV antibody test with a follow up HCV viral test, and if HCV viremia is detected, treatment is initiated within three months or receives a referral to a clinician who treats HCV infection within one month of the reactive HCV antibody test **DENOMINATOR (Submission Criteria 2):** Patients >= 18 years of age who are seen twice for any visits OR who have at least one preventive visit AND have documentation of a reactive HCV antibody test between January 1 and September 30 of the performance period. Denominator Criteria (Eligible Cases): Patients aged ≥ 18 years of age **AND** All eligible instances when GXXXX is submitted for Performance Met (patient receives HCV antibody test and the test is reactive) in the numerator of Submission Criteria 1 **AND** At least one preventive encounter **OR** At least two patient encounters **Updated denominator note: Added:** For submission criteria 1: Either documentation of the prior HCV antibody test or HCV RNA test in the medical record or patient self-report of prior HCV antibody test or HCV RNA test is acceptable for this exclusion. **Updated numerator: Revised:** For submission criteria 1: Patients who receive an HCV antibody test between January 1 and September 30 of the performance period. **Added:** For submission criteria 2: Patients who have an HCV viral test conducted that (a) does not detect HCV viremia, or (b) detects HCV viremia and treatment is initiated within three months or they are referred to a clinician who treats HCV infection within one month of the reactive HCV antibody test. **Updated definitions:** **Removed:** For submission criteria 1: definition for screening for HCV Infection includes current or prior receipt of **Added:** For submission criteria 2: **Definition:** Examples of clinicians who treat HCV infection include but are not limited to: • Gastroenterologist • Hepatologist • Infectious disease clinicians Initiation of treatment definition for clinicians who do not refer patients to specialists for care: • Initiation of antiviral treatment, as appropriate, based on clinical guideline recommendations and patient characteristics. HCV viral test is defined as a test measuring an established marker of active HCV infection, including: • HCV RNA test • HCV core antigen test **Updated numerator options:** **Revised:** For submission criteria 1: **Performance Met:** Patient receives an HCV antibody test with nonreactive result **Performance Met:** Patient receives an HCV antibody test with reactive result **Denominator Exception:** Documentation of medical reason(s) for not receiving HCV antibody test due to limited life expectancy **Performance Not Met:** Patient does not receive HCV antibody test OR patient does receive HCV antibody test but results not documented, reason not given **Added:** For submission criteria 2: **Performance Met:** Patient, who has a reactive HCV antibody test, and has a follow up HCV viral test that detected HCV viremia, is referred within 1 month of the reactive HCV antibody test to a clinician who treats HCV infection **Performance Met:** Patient, who has a reactive HCV antibody test, and has a follow up HCV viral test that detected HCV viremia, has HCV treatment initiated within 3 months of the reactive HCV antibody test **Performance Met:** Patient has a reactive HCV antibody test, and has a follow up HCV viral test that does not detect HCV viremia **Performance Not Met:** Patient has a reactive HCV antibody test and does not have a follow-up HCV viral test, OR Patient has a reactive HCV antibody test and has a follow up HCV viral test that detects HCV viremia and is not referred to a clinician who treats HCV infection within 1 month and does not have HCV treatment initiated within 3 months of the reactive HCV antibody test, reason not given
Measure Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise this measure to include follow up testing for HCV and, if viremia is detected, that treatment is initiated, or patients are referred to a clinician who treats HCV infection. This will be accomplished by stratifying the measure to create submission criteria (with corresponding performance rate) for patients who have never been tested for HCV antibodies and who receive an HCV test, and a submission criterion (with corresponding performance rate) for patients who have a reactive HCV

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	antibody test and, if HCV viremia detected, have treatment initiated or referral for treatment. This revision would be reflected within multiple components within the specification. These revisions take the measure one step further to ensure actions are being taken once the screening is completed so patients receive the appropriate care resulting in positive health outcomes. We would continue to monitor this measure throughout the rulemaking process for testing being performed by the measure steward regarding these proposed changes to the measure. Finalization of these revisions are contingent on completion of this testing. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.46 Clinical Outcome Post Endovascular Stroke Treatment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	409
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.
Substantive Change:	**Updated denominator exclusion: Added:** For Submission Criteria 1: Exclude patients with a baseline mRS > 2
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to add a denominator exclusion for Submission Criteria 1 to account for patients who have a baseline mRS of greater than 2 as endovascular stroke intervention would not be clinically indicated for this patient population.[451]

[451] American Heart Association, American Stroke Association. Acute Ischemic Stroke: Current Treatment Approaches for Acute Ischemic Stroke [PowerPoint slides]. *https://www.stroke.org/-/media/Stroke-Files/Ischemic-Stroke-Professional-Materials/AIS-Toolkit/AIS-Professional-Education-Presentation-ucm_485538.*

D.47 Osteoporosis Management in Women Who Had a Fracture

Category	Description
CBE # / eCQM CBE #:	0053 / N/A
Quality #:	418
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator criteria: Added: For all** submission criteria: coding for nonphysician, physician, and qualified health care professional (QHP) telephone assessments, and federally qualified health center (FQHC) visit.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	Additionally, we propose to update the measure to include coding for telephone assessments with nonphysician/QHPs, and federally qualified health center (FQHC) visits within the denominator eligible encounter criteria as this measure is applicable to the scope of care given by these clinicians.

D.48 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
CBE # / eCQM CBE #:	2152 / N/A
Quality #:	431
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.
Substantive Change:	**Updated measure analytic: Revised:** data completeness will be determined utilizing submission criteria one.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the analytic of the measure to utilize submission criteria one for the determination of data completeness to ensure a complete data submission for all denominator eligible patients for this measure. As submission criteria two only includes those patients identified as unhealthy alcohol users, the intent of the measure is to also ensure screening of all patients aged 18 years and older. Assessing data completeness utilizing submission criteria one will ensure that screening information was collected.

D.49 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	438
CMS eCQM ID:	CMS347v7
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • All patients who were previously diagnosed with or currently have a diagnosis clinical atherosclerotic cardiovascular disease (ASCVD) including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40-75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated rate aggregation: For the eCQM Specifications collection type:** **Revised:** Population 2: Patients aged 20 to 75 years at the beginning of the measurement period **Added:** Population 4: Patients aged 40 to 75 at the beginning of the measurement period with a 10-year ASCVD risk score of > = 20 percent during the measurement period. **Revised:** Performance Rate to aggregate all 4 populations into a single performance rate. **Updated guidance: For the eCQM Specifications collection type: Revised:** the process to prevent counting patients more than once. **Updated denominator: For all collection types: Revised**: DENOMINATOR (SUBMISSION CRITERIA 2): Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. **Added:** DENOMINATOR (SUBMISSION CRITERIA 4): Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period. **Updated instructions: For the MIPS CQMs Specification collection type: Revised:** THERE ARE FOUR SUBMISSION CRITERIA FOR THIS MEASURE**: 1) All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure. OR 2) Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. OR 3) Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. OR 4) Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of > 20 percent. **Revised:** There is only one performance rate calculated for this measure. Patients can only be counted once and cannot be in more than one **submission criteria**. When submitting this measure, determine if the patient meets denominator eligibility in order of each risk category defined in the denominator submission criteria. For example, first evaluate if the patient meets denominator Submission Criteria 1. If no, then evaluate if the patient meets denominator Submission Criteria 2. If yes, then the patient will be in Submission Criteria 2 and is not eligible for denominator Submission Criteria 3 and 4. **Updated initial patient population: For the eCQM Specifications collection type:** Population 1: All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD or ever had, including an ASCVD procedure. Population 2: Patients aged >= 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. Population 4: Patients aged 40 to 75 at the beginning of the measurement period with 10-year ASCVD risk score (i.e., 2013 ACC/AHA ASCVD Risk Estimator or the ACC Risk Estimator Plus) of >= 20 percent during the measurement period. **Updated denominator criteria: For the MIPS CQM Specifications collection type:** **Revised:** For submission criteria 2: Patient aged 20 to 75 years at the beginning of the measurement period.

Category	Description
	Added: For submission criteria 4: Patients aged 40 through 75 years at the beginning of the measurement period AND Calculated 10-year ASCVD risk score of ≥ 20 percent during the measurement period AND Patient encounter during the performance period AND NOT DENOMINATOR EXCLUSIONS: Patients who are breastfeeding at any time during the measurement period OR Patients who have a diagnosis of rhabdomyolysis at any time during the measurement period **Updated numerator: For the MIPS CQM Specifications collection type: Added:** (SUBMISSION CRITERIA 4): Patients who are actively using or who receive an order (prescription) for statin therapy at any time during the measurement period. **Updated denominator exception: For the MIPS CQMs Specifications collection type: Added:** For submission **criteria** 4: Denominator Exceptions 1. Active Liver or Hepatic Disease or Insufficiency 2. End Stage Renal Disease 3. Statin-Associated Muscle Symptoms (SAMS) **Updated numerator definition: For the MIPS CQM Specification collection type: Added:** For submission criteria 4: Statin therapy Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. **Updated numerator note: For the MIPS CQM Specification collection type: Added:** For submission criteria 4: In order to meet the measure, current statin therapy use must be documented in the patient's current medication list or ordered during the measurement period. Only statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). Prescription or order does NOT need to be linked to an encounter or visit; it may be called to the pharmacy. Statin medication "samples" provided to patients can be documented as "current statin therapy" if documented in the medication list in health/medical record. Patients who meet the denominator criteria for inclusion but are not prescribed or using statin therapy will NOT meet performance for this measure. Adherence to statin therapy is not calculated in this measure. It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions for the complete list). Intensity of statin therapy in primary and secondary prevention: The expert panel of the 2018 ACC/AHA/MS Guidelines [1] defines recommended intensity of statin therapy on the basis of the average expected LDL-C response to specific statin and dose. Although intensity of statin therapy is important in managing cholesterol, this measure assesses prescription of ANY statin therapy, irrespective of intensity. Assessment of appropriate intensity and dosage documentation added too much complexity to allow inclusion of statin therapy intensity in the measure at this time. Denominator Exceptions should be active during the measurement period. **Updated numerator options: For the MIPS CQM Specification collection type: Added:** For **submission criteria** 4: **Performance Met:** Patients who are currently statin therapy users or received an order (prescription) for statin therapy **Denominator Exception:** Documentation of medical reason(s) for not currently being a statin therapy user or receiving an order (prescription) for statin therapy (e.g., patient with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice care, patients with active liver disease or hepatic disease or insufficiency, patients with end stage renal disease [ESRD] or other medical reasons) **Performance Not Met:** Patients who are not currently statin therapy users or did not receive an order (prescription) for statin therapy
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure that would allow it to align more closely with the 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.[452] Submission criteria one was updated to reflect a cap in the age denominator criteria to 75. The ACC/AHA 2018 cholesterol guidelines state that in adults older than 75 years with diabetes mellitus, it may be reasonable to initiate statin therapy after a clinician–patient discussion of potential benefits and risks for prevention of ASCVD events.[453] Additionally we proposed to add submission criteria 4, which specifically assesses statin use for patients that have a 10-

[452] Arnett, D. K., Blumenthal, R. S., Albert, M. A., Buroker, A. B., Goldberger, Z. D., Hahn, E. J., & Ziaeian, B. (2019). 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 140(11), e596-e646. *https://doi.org/10.1161/CIR.0000000000000678*.

[453] Saeed, A. & Mehta, L. (2020, October 1). Statin Therapy in Older Adults for Primary Prevention of Atherosclerotic Cardiovascular Disease: The Balancing Act. *https://www.acc.org/latest-in-cardiology/articles/2020/10/01/11/39/statin-therapy-in-older-adults-for-primary-prevention-of-atherosclerotic-cv-disease*.

Category	Description
	year ASCVD risk score of > 20 percent. Patients that meet this denominator criteria would be considered high risk and based on the guidelines, should be strongly recommended statin therapy solely based on risk alone and after a clinician patient risk discussion.[454] Furthermore, we propose to update the description and measure instructions to clearly communicate the changes within submission criteria one and the inclusion of a submission criteria 4. Due to the proposal of submission criteria 4, we propose to revise the measure instructions to explain to interested parties how this measure would be calculated for the purpose of MIPS. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark would be used for scoring.

D.50 Non-Recommended Cervical Cancer Screening in Adolescent Females

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	443
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.
Substantive Change:	**Updated denominator exclusion: Added:** coding for Cytokine Release Syndrome.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator exclusions criteria by adding ICD-10-CM codes for Cytokine Release Syndrome, which would allow clinicians to capture and exclude patients with Cytokine Release Syndrome, as it may be appropriate for these patients to receive cervical cancer screening. It would also create alignment with the HEDIS measure.

D.51 Appropriate Workup Prior to Endometrial Ablation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	448
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.
Substantive Change:	**Updated denominator criteria: Removed:** coding for extraction of endometrium.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove ICD-10 codes 0UDB7ZZ and 0UDB8ZZ from the denominator criteria as these codes do not represent endometrial ablation, but rather endometrial extraction. This change would ensure that the patients included within the denominator would truly meet the intent of the measure. Additionally, it would ensure all patients undergoing this procedure are included within the denominator to be assessed for the quality action described in the numerator.

D.52 Functional Status After Primary Total Knee Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	470
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Postoperative Assessment Oxford Knee Score (OKS) or KOOS, JR - A postoperative Oxford Knee Score (OKS) or KOOS, JR functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to 9 months and after 15 months postoperatively will not be used for measure calculation.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the numerator definition to add KOOS, JR. The "KOOS, JR." was developed from the original long version of the Knee injury and Osteoarthritis Outcome Score (KOOS) survey using Rasch analysis. The "KOOS, JR." contains seven items from the original KOOS survey. Items are coded from 0 to 4, none to extreme respectively. "KOOS, JR." is scored by summing the raw response (range 0-28) and then converting it to an interval score using the table provided below. The interval score ranges from 0 to 100 where 0 represents total knee disability and 100 represents perfect knee health. This short form tool was developed in 2017 (*https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp*). Additionally, the language has been revised and would allow for assessments completed via telephone.

D.53 HIV Screening

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	475
CMS eCQM ID:	CMS349v6
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).
Substantive Change:	**Updated denominator exception: Added:** Patients who die on or before the end of the measurement period.
Measure Steward:	Centers for Disease Control and Prevention
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add a denominator exception for patients who die before receiving an HIV screening. Since it is possible that a clinician could advance schedule an HIV test for a patient who potentially may die prior to the test, allowing this denominator exception would preserve performance of reporting clinicians while maintaining the intent of the measure.

D.54 Psoriasis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	485
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit
Substantive Change:	**The description is revised to read:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit. **The measure denominator is revised to read:** All patients aged 8 years and older, with a diagnosis of psoriasis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit. **Updated denominator definition:** **Revised:** patient age to 8 years and older on date of service **Added:** Visual Rating Scale (VRS) for Pruritis – Note: (**This scale is intended for patients 18 years and older**) **Updated numerator: Revised:** required assessment score change from 2 or more points to 3 or more points. **Updated numerator options: Revised:** required assessment score change from 2 or more points to 3 or more points.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the denominator and the denominator criteria to change the age from 18 years and older to 8 years and older. We also propose to add a note to the Visual Rating Scale (VRS) for Pruritis definition as this tool is only validated for patients 18 years and older. We propose a reduction in assessment score from 2 or more points to 3 or more points to align with current clinical guidelines. This skin condition has an annual prevalence of up to 0.71 percent within the pediatric patient population. Therefore, inclusion of the pediatric patient population would provide support for this frequently seen chronic inflammatory skin disorder and have significant impact on their overall quality of life (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683294/*).

D.55 Dermatitis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	486
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.
Substantive Change:	**The description is revised to read:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit. **The measure denominator is revised to read:** All patients aged 8 years and older, with a diagnosis of psoriasis with an initial (index visit) Numeric Rating Scale (NRS), Visual Rating Scale (VRS), or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit. **Updated denominator definition: Removed:** Visual Rating Scale (VRS) for Pruritis. **Updated denominator criteria:** **Revised:** patient age to 8 years and older on date of service **Added:** Visual Rating Scale (VRS) for Pruritis – Note: (**This scale is intended for patients 18 years and older**) **Updated numerator: Revised:** required assessment score change from 2 or more points to 3 or more points. **Updated numerator options: Revised:** required assessment score change from 2 or more points to 3 or more points.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the denominator and the denominator criteria to change the age from 18 years and older to 8 years and older. We also propose to add a note to the VRS for Pruritis definition as this tool is only validated for patients 18 years and older. We propose a reduction in assessment score from 2 or more points to 3 or more points to align with current clinical guidelines. Optimizing management of dermatitis in pediatric patients is critical to reduce signs of inflammation, alleviate pruritus and sleep disturbance, minimize the development and/or impact of comorbidities, and improve the patient and caregiver's quality of life (*https://pubmed.ncbi.nlm.nih.gov/33838839/*).

D.56 Screening for Social Drivers of Health

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	487
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
Substantive Change:	**Updated denominator criteria: Added:** coding for occupational therapy. **Updated denominator exception:** **Added:** **Denominator Exception:** Patient reason for not screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety (e.g., patient declined or other patient reasons)
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add encounter codes for MIPS eligible occupational therapists based upon interested parties' feedback: "Occupational therapy practitioners across practice settings should consider how current housing status and social determinants of health may impact their clients' occupational performance and ability to manage health conditions" (*https://pubmed.ncbi.nlm.nih.gov/32007967/*). We also propose to include a denominator exception as some patients may prefer not to discuss this information, however, attempting to screen every patient is important.

D.57 Adult Immunization Status

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	493
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Substantive Change:	**Updated denominator:** **Removed:** For all submission criteria: Active chemotherapy during the measurement period OR Bone marrow transplant during the measurement period OR History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & Hemoglobin (HB)-S disease or cerebrospinal fluid leaks any time during the patient's history prior to or during the measurement period: • Anatomic or Functional Asplenia • Cerebrospinal Fluid Leak • Cochlear Implant • Cochlear Implant Device • Cochlear Implant Diagnosis • Immunocompromising Conditions • Sickle Cell Anemia and HB-S Disease **Updated denominator exception:** **Added:** For submission criteria 3: Documentation that administration of second recombinant zoster vaccine could not occur during the performance period due to the recommended 2-6 month interval between doses (i.e., first dose received after October 31)
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove denominator exclusions for all submission criteria for patients receiving active chemotherapy, who have a bone marrow transplant, or history of immunocompromising conditions as these are not contraindicators for receiving these vaccines and is in alignment with ACIP recommendations (*https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html*). We propose to add a denominator exception if there is a system reason that the second dose of recombinant zoster vaccine could not be administered within the prescribed interval during the performance period, as there is a minimum interval requirement between doses.

Table Group DD: Previously Finalized Quality Measures with Substantive Changes Proposed for Partial Removal as Component Measures in Traditional MIPS and Proposed for Retention for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

As noted under Table Group CC of this Appendix, beginning with the CY 2024 performance period/2026 MIPS payment year and future years, we propose to maintain measures Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan for MIPS Value Pathways (MVP) development, and maintain measures Q112 and Q113 for purposes of Shared Savings Program ACOs reporting through the APP as discussed in section III.G.2.c.(2) of this proposed rule. These measures have proposed substantive changes under Table Group DD and Table Group E of this Appendix.

Note: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE # / eCQM CBE #.

The DD Tables within this proposed rule provide the substantive changes proposed for the quality measures in CY 2024. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2024 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2024 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2025. The 2023 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2024 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2024 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, would the DD table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

Note: For the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface measures as a collection type is only available for APM Entities, specifically Shared Savings Program ACOs reporting through the APP (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS). Thus, the CMS Web Interface collection type collection type is not listed in any table under Table Group DD of this Appendix. For further information regarding the Shared Savings Program requirements under the APP and the CMS Web Interface collection type available under the APP, see section III.G.2.c.(2) of this proposed rule. For information regarding proposed changes to the CMS Web Interface measures for the CY 2024 performance period/2026 MIPS payment year, see Table Group E of this Appendix.

We request comments on these substantive changes.

DD.1 Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated measure description: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 40 – 74. **Updated denominator: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 41 – 74. **Updated denominator criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Patient age to 41 – 74. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore would align with intent of the measure to exclude patients with this condition from the measure. Additionally, we propose to update the denominator eligible age criteria for this measure to align with the May 2023 draft recommendation statement issued by the USPSTF.[455]

DD.2 Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v12
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore would align with intent of the measure to exclude patients with this condition from the measure.

Table Group E: Previously Finalized CMS Web Interface Quality Measures with Substantive Changes Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

The E Tables within this proposed rule provide the substantive changes proposed for the CMS Web Interface quality measures in CY 2024. It should be noted that for the CY 2024 performance period/2026 MIPS payment year (and prior CY 2023 performance period/2025 MIPS payment year), the CMS Web Interface as a collection type is only available for APM Entities, specifically Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting through the APM Performance Pathway (APP) (the CMS Web Interface measures as a collection type is no longer available under traditional MIPS).

The changes that are made to the code sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2024 may not be identified within the proposed rule due to the availability of these changes to the public. The 2024 CMS Web Interface Measure Coding Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to stakeholders. These changes align with the scope of the current coding; however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2024 CMS Web Interface Measure Coding Release Notes once posted to review all coding changes.

The 2024 eCQM collection type measures had substantive changes that could prove burdensome to collect, therefore, the CMS Web Interface specifications will align with the 2024 MIPS CQMs specifications changes for these measures.

The tables below contain proposed **changes for performance year** 2024 CMS **Web Interface measure specifications to be used in the Shared Savings Program** for **quality reporting.** Note: there are substantive changes proposed for 9 of the 10 CMS Web Interface measures.

E.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE #	0059
Quality #:	001 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	DM-2
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to the list of dementia medication exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.

E.2 Preventive Care and Screening: Influenza Immunization

Category	Description
CBE #	0041
Quality #:	110 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-7
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Updated denominator exclusion criteria: Added:** Anaphylaxis due to the vaccine on or before the measurement period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion by adding an exclusion for patients who experienced anaphylaxis due to the vaccine. While anaphylaxis due to the flu vaccine is rare, patients who have previously experienced a severe allergic reaction due to the influenza vaccine, regardless of the component suspected of being responsible for the reaction, shouldn't receive additional doses of the vaccine (*https://www.cdc.gov/flu/prevent/egg-allergies.htm#:~:text=A%20person%20who%20has%20previously,get%20a%20flu%20vaccine%20again*).

E.3 Breast Cancer Screening

Category	Description
CBE #	2372
Quality #:	112 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-5
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated measure description: Revised:** Patient age to 40 – 74. **Updated denominator: Revised:** Patient age to 41 – 74. **Updated initial population: Revised:** Patient age to 41 – 74. **Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. Additionally, we propose to update the denominator eligible age criteria for this measure to align with the May 2023 draft recommendation statement issued by the USPSTF for breast cancer screening.[456]

[456] USPSTF (2023). Task Force Issues Draft Recommendation Statement on Screening for Breast Cancer. *https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/breast-cancer-screening-draft-rec-bulletin.pdf*.

E.4 Colorectal Cancer Screening

Category	Description
CBE #	0034
Quality #:	113 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface:	PREV-6
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia exclusion medications, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure.

E.5 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE #	N/A
Quality #:	134 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-12
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**Updated guidance: Revised:** The intent of the measure is to screen for new cases of depression in patients who have never had a diagnosis of bipolar disorder prior to the qualifying encounter used to evaluate the numerator. Patients who have ever been diagnosed with bipolar disorder will be excluded from the measure. **Updated denominator exclusion: Removed:** Diagnosis of depression from the denominator exclusion. **Updated denominator criteria: Added:** coding for qualifying encounters for nutritionists/dieticians and home-based health care.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion and applicable measure guidance to remove a previous diagnosis of depression as an exclusion, as patients with a history of depression clinically may require more frequent monitoring and ongoing treatment for reoccurrence of symptoms. We propose to update the denominator to include encounter codes for nutritionists and dieticians, as well as home-based encounter codes, as it is clinically appropriate to conduct depression screenings during these encounters.

E.6 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
CBE #	0028
Quality #:	226 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-10
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients aged 18 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 12 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 12 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months. **The initial population is revised to read:** All patients aged 12 years and older seen for at least two visits or at least one preventive visit during the measurement period
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure to lower the denominator eligible age to 12 years and older to allow for the inclusion of adolescents into the measure's denominator. Lowering the denominator eligible age aligns with proposed changes for all other collection types, which combine the patient population within measure Q402: Tobacco Use and Help with Quitting Among Adolescents with that of measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention resulting in a single, more robust measure.

E.7 Controlling High Blood Pressure

Category	Description
CBE #	N/A
Quality #:	236 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	HTN-2
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**The measure initial patient population is revised to read:** Patients 18-85 years of age who had a visit during the measurement period and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period. **Updated denominator exclusion: Added:** Dementia combinations: Donepezil-memantine to list of dementia exclusion medications. **Updated guidance: Revised:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. **Updated numerator note: Revised:** In reference to the numerator element, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to revise the initial patient population to specify the patient visit must occur during the measurement period. This revision provides clarification of the encounter timing. Additionally, we propose to update the denominator exclusion to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. We propose to revise the measure guidance and the numerator note around remote monitoring devices for capturing blood pressure readings. Currently, the measure allows patient reported data using most methods of digital collection/reporting and prohibits patient reported data taken with non-digital devices, such as with a manual blood pressure cuff and stethoscope. The measure is agnostic to how the reading gets in and the documentation practice of each office; therefore, whether patient is "conveying the reading to the clinician" by manually entering the BP reading (for example, patient portal) or having the device auto-transmit data directly, it is the clinician's responsibility and discretion to confirm that the automated blood pressure monitor used to obtain the blood pressure is considered acceptable and reliable.

E.8 Depression Remission at Twelve Months

Category	Description
CBE #	0710
Quality #:	370 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	MII-1
Current Collection Type:	CMS Web Interface
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event.
Substantive Change:	**Updated denominator exclusion: Removed:** Exclusion for patients who were permanent nursing home residents during the denominator identification period or the measure assessment period.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to remove the denominator exclusion related to patients who were permanent nursing home residents. This component has an extremely low rate of use, demonstrating that it's not a meaningful exclusion for the measure.

E.9 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE #	N/A
Quality #:	438 (as previously associated with a Quality # prior to the sunset of the CMS Web Interface collection type under MIPS that became effective starting with the CY 2023 performance period)
CMS Web Interface ID:	PREV-13
Current Collection Type:	CMS Web Interface
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes
Substantive Change:	**The measure description is revised to read:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • All patients who were previously diagnosed with or currently have a diagnosis clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated denominator guidance:** **Revised:** Denominator Population Guidance: The denominator population covers four distinct populations. There is only one performance rate calculated for this measure. Use the following process to prevent counting patients more than once. Denominator Population 1: All patients who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure before the end of the measurement period If YES, patient meets Denominator Population 1 risk category If NO, screen for next risk category Denominator Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia If YES, patient meets Denominator Population 2 risk category If NO, screen for next risk category Denominator Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with a diagnosis of Type 1 or Type 2 diabetes at any time during the measurement period If YES, patient meets Denominator Population 3 risk category If NO, screen for next risk category Denominator Population 4: Patients aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period If YES, patient meets Denominator Population 4 risk category If NO, patient does NOT meet denominator criteria and is NOT eligible for measure inclusion.

Category	Description
	Added: For Denominator Population Guidance for Encounter: To meet Denominator Population 4: There is no LDL-C result required. **Removed:** For Denominator Population Guidance for Encounter: Lifestyle modification coaching: A healthy lifestyle is important for the prevention of cardiovascular disease. However, lifestyle modification monitoring and documentation added too much complexity to allow its inclusion in the measure at this time. **The initial population is revised to read:** Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD or ever had, including an ASCVD procedure. Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. Population 4: Patients aged 40 to 75 at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent **Updated denominator:** **Revised:** Population 2: Patients aged 20 to 75 years at the beginning of the measurement period who have ever had laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia **Added:** Population 4: Patients aged 40 to 75 at the beginning of the performance period with a 10-year ASCVD risk score of ≥ 20 percent during the performance period. **Updated numerator definition: Added:** 10 Year Risk Assessment - The 10-year ASCVD risk score is calculated using the Pooled Cohort Equations: 1) the 2013 ACC/AHA ASCVD Risk Estimator OR 2) the ACC Risk Estimator Plus. If your EHR does not have either of these risk calculators, we recommend that you use the on-line versions. The 10-year ASCVD risk assessment must be performed during the measurement period **Updated submission guidance: Revised:** DENOMINATOR CONFIRMATION, POPULATION 2 ○ Determine if the patient is aged 20 to 75 years at the beginning of the measurement period AND has ever had a laboratory result of LDL-C ≥ 190 mg/dL OR were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia ○ If the patient is 20 to 75 years at the beginning of the measurement period AND has ever had a laboratory result of LDL-C ≥ 190 mg/dL documented OR were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia select "Yes" **OR** ○ If the patient is not 20 to 75 years at the beginning of the measurement period OR has never had a laboratory result of LDL-C ≥ 190 mg/dL AND has never been previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia documented select "No Diagnosis" **Added:** DENOMINATOR CONFIRMATION, POPULATION 4 ○ Determine if the patient is aged 40 to 75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period ○ If the patient is aged 40-75 years at the beginning of the measurement period with a 10-year ASCVD risk score of ≥ 20 percent during the measurement period select "Yes" **OR** ○ If the patient is not aged 40 to 75 years at the beginning of the measurement period or does not have a 10-year ASCVD risk score of ≥ 20 percent during the measurement period select "No – Risk Assessment" **OR** ○ If there is a denominator exclusion for patient disqualification from the measure select "Denominator Exclusion" **OR** ○ If there is an "other" CMS approved reason for patient disqualification from the measure select "No- Other CMS Approved Reason"
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose revisions to this measure that would allow it to align more closely with the 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on

Category	Description
	Clinical Practice Guidelines.[457] We propose to update submission criteria 2 to reflect a cap in the age denominator criteria to 75. The ACC/AHA 2018 cholesterol guidelines state that in adults older than 75 years with diabetes mellitus, it may be reasonable to initiate statin therapy after a clinician–patient discussion of potential benefits and risks for prevention of ASCVD events.[458] Additionally we propose to add submission criteria 4, which specifically assesses statin use for patients that have a 10-year ASCVD risk score of > 20 percent. Patients that meet this denominator criteria would be considered high risk and based on the guidelines, should be strongly recommended statin therapy solely based on risk alone and after a clinician patient risk discussion.[459] Furthermore, we propose to update the description and measure instructions to clearly communicate the changes within submission criteria one and the inclusion of a submission criteria 4.

APPENDIX 2: IMPROVEMENT ACTIVITIES

In this proposed rule, for the CY 2024 performance period/2026 MIPS payment year and future years, we are proposing to add five new improvement activities, modify one previously adopted improvement activity, and remove three previously adopted improvement activities. These proposals are discussed in section IV.A.4.f. of this proposed rule and in more detail below. We request comment on our proposals.

Table A: New Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
Proposed Activity Description:	Establish policies and procedures to improve practice capacity to increase HIV prevention screening, improve HIV prevention education and awareness, and reduce disparities in pre-exposure prophylaxis (PrEP) uptake. Use one or more of the following activities: • Implement electronic health record (EHR) prompts or clinical decision support tools to increase appropriate HIV prevention screening; • Require that providers and designated clinical staff take part in at least one educational opportunity that includes components on the importance and application of HIV prevention screening and PrEP initiation in clinical practice; and/or • Assess and refine current policies for HIV prevention screening, including integrated sexually transmitted infection (STI)/HIV testing processes, universal HIV screening, and PrEP initiation.
Proposed Weighting:	Medium
Rationale:	The Centers for Disease Control and Prevention (CDC) estimates that nearly 1.2 million Americans are living with HIV and that nearly one in eight are not aware that they are infected.[10,11] Social determinants of health (SDOH) factors, including low socioeconomic status, living in poverty, lack of transportation to care services, low health literacy levels

[457] Arnett, D. K., Blumenthal, R. S., Albert, M. A., Buroker, A. B., Goldberger, Z. D., Hahn, E. J., Himmelfarb, C. D., Khera, A., Lloyd-Jones, D., McEvoy, J. W., Michos, E. D., Miedema, M. D., Muñoz, D., Smith, S. C., Jr, Virani, S. S., Williams, K. A., Sr, Yeboah, J., & Ziaeian, B. (2019). 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 140(11), e596–e646. *https://doi.org/10.1161/CIR.0000000000000678*.

[458] Saeed, A. & Mehta, L. (2020, October 1). Statin Therapy in Older Adults for Primary Prevention of Atherosclerotic Cardiovascular Disease: The Balancing Act. *https://www.acc.org/latest-in-cardiology/articles/2020/10/01/11/39/statin-therapy-in-older-adults-for-primary-prevention-of-atherosclerotic-cv-disease*.

[459] Arps, K., Blumenthal, R., & Martin, S. (2018, November 15). New Aspects of the Risk Assessment Guidelines, Scientific Evidence and Future Goals. *https://www.acc.org/latest-in-cardiology/articles/2018/11/14/07/10/new-aspects-of-the-risk-assessment-guidelines*.

	to complete medical forms, homelessness, and intimate partner violence can lead to limitations in seeking preventive measures, including accessing healthcare providers or HIV testing sites.[40] The CDC recommends that all individuals between the ages of 13 and 64 get tested for HIV at least once as part of routine healthcare.[13] Individuals at greater risk, including gay, bisexual, and other men who have sex with men (MSM), and persons who inject drugs, are recommended for more frequent, annual HIV screening.[12,13] The CDC also recommends that all sexually active adult and adolescent patients should receive information about HIV pre-exposure prophylaxis (PrEP), and recommends PrEP as an effective HIV prevention strategy.[14] Taking PrEP as prescribed reduces the risk of transmitting HIV through sexual contact by about 99 percent, and limits the risk of acquiring HIV by at least 74 percent among people who inject drugs.[14] Lack of HIV preventive care and referrals among vulnerable populations in the U.S. leads to inequities in access to HIV prevention treatment.[30,36] One study reported that fewer Black, Hispanic, or Latino people who tested negative for HIV and were eligible for PrEP received a referral for treatment as compared with other racial and ethnic groups.[36] Among both males and females, Black and Hispanic people have far lower PrEP uptake rates relative to their risk than do White males, a disparity that is starkest among Black males.[29] Despite MSM representing the highest proportion of Americans diagnosed with HIV, lack of awareness and understanding of PrEP has led to low rates of PrEP use among this group; in one study conducted among Black/African American and white PrEP-eligible MSM, 61 percent were aware of PrEP, but only 9 percent used it.[36] In another study conducted among Black/African American MSM, PrEP awareness was 39 percent, but actual use was less than 5 percent.[36] Barriers to PrEP uptake have contributed to low rates of use, with more than one-half of PrEP-eligible MSM being reported as failing to reach the contemplation stage (for example, willing and self-identified as appropriate candidates) of PrEP adoption.[34] Implementation of an electronic HIV screening alert almost doubled the rates of universal HIV screening in one study of primary care providers in a Midwestern practice and this implementation also reduced racial disparities in care.[38] Provider knowledge about PrEP was associated with both past and potential future initiation of PrEP, and an observed greater willingness to prescribe PrEP was associated with higher PrEP knowledge.[7] HIV diagnoses in MSM in New South Wales, Australia, declined from 295 (cases) in the 12 months before PrEP roll-out to 221 (cases) in the 12 months after roll-out. Grulich and colleagues (2018) also observed a decline both in recent HIV infections (from 149 cases to 102) and in other HIV-related diagnoses.[27] This HIV prevention-focused activity, including clinician education, will help to narrow gaps and inequities in care related to HIV prevention in clinical practice, and that it will highlight HIV prevention guidelines, including recommendations to enhance prevention screening and PrEP awareness and use. We propose weighting this activity medium, because this activity may be accomplished by establishing or refining policies and procedures to improve practice capacity to increase HIV prevention screening and linkage to appropriate prevention resources. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 and 59781).
New Improvement Activity	
Proposed Activity ID:	**IA__MVP**
Proposed Subcategory:	N/A
Proposed Activity Title:	Practice-Wide Quality Improvement in MIPS Value Pathways
Proposed Activity Description:	Create a quality improvement initiative within your practice and create a culture in which all staff actively participates. Clinicians must be participating in MIPS Value Pathways (MVPs) to attest to this activity.

	Create a quality improvement plan that involves a minimum of three of the measures within a specific MVP and that is characterized by the following: • Train all staff in quality improvement methods, particularly as related to other quality initiatives currently underway in the practice; • Promote transparency and accelerate improvement by sharing practice-level and panel-level quality of care and patient experience and utilization data with staff; • Integrate practice change/quality improvement into all staff duties, including communication and education regarding all current quality initiatives; • Designate regular team meetings to review data and plan improvement cycles with defined, iterative goals as appropriate; or • Promote transparency and engage patients and families by sharing practice-level quality of care and patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data. In addition, clinicians may consider: • Creation of specific plans for recognition of individual or groups of clinicians and staff when they meet certain practice-defined quality goals. Examples include recognition for achieving success in measure reporting and/or a high level of effort directed to quality improvement and practice standardization; and • Participation in the American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Proposed Weighting:	High
Rationale:	Clinical practice quality improvement (QI) activities are commonly limited to staff members directly involved in the performance of the specific activity. Creating a culture of QI among all staff working as a team drives outcomes more effectively than when the work is done in isolation. This collaborative approach allows for a more comprehensive view of QI goals and, in turn, the development of most efficient and effective initiatives. Additionally, the positive and unpredictable ideas that come from a high-functioning collaborative team can be crucial to achieving QI that is most meaningful to both patients and providers. Creating coordination between the goals of this activity and the goals of the measures within an MVP will create an intuitive focus within a specific clinical area, which will allow clinicians and other staff members to be most productive in their QI efforts. This coordinated clinical focus is likely to lessen the perceived burden of MIPS and MVP while the effort required will still be sufficiently high. Team-based quality improvement approaches have been found to be highly effective in healthcare.[18,32] In addition, this activity will incentivize voluntary MVP adoption, which will drive clinician accountability and quality improvement on factors that are more relevant to their practice. For a discussion of the benefits of MVPs, please see the 2021 PFS final rule (85 FR 84844 through 84846). We propose making this activity high-weighted because MIPS eligible clinicians will need considerable time and resources to implement practice-wide quality improvement via MVPs. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 and 59781). While this MVP-only activity could appear duplicative on the surface, this MVP activity specifically defines the nature of the QI project that clinicians must complete, and it is particular to the measures they are reporting on in the MVP they have chosen. We are requiring clinicians complete the project focused on three separate measures. In contrast, IA_PSPA_19 requires only a focused single improvement. This is consistent with the work that clinicians will need to complete to be successful with MVPs.
New Improvement Activity	
Proposed Activity ID:	**IA_PM_XX**

Proposed Subcategory:	Population Management
Proposed Activity Title:	Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines
Proposed Activity Description:	Incorporate the Cervical Cancer Screening and Management (CCSM) Clinical Decision Support (CDS) tool within the electronic health record (EHR) system to provide clinicians with ready access to and assisted interpretation of the most up-to-date clinical practice guidelines in CCSM to ensure adequate screening, timely follow-up, and optimal patient care. The CCSM CDS helps ensure that patient populations receive adequate screening and management, according to evidence-based recommendations in the United States Preventive Services Task Force (USPSTF) screening and American Society for Colposcopy and Cervical Pathology (ASCCP) management guidelines for cervical cancer. The CDS integrates into the clinical workflow a clinician-facing dashboard to support the clinician's awareness and adoption of and preventive care for cervical cancer, including screening and any necessary follow-up treatment. The CCSM CDS is fully conformant with the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, so it can be used with any certified EHR platform. The CDS Hooks and SMART-on-FHIR interoperability interface standards provide two ways to integrate with the clinical workflow in a way that complements existing displays and information pre-visit, during visit, and for post-visit follow-up. CCSM CDS helps the clinician evaluate the patient's clinical data against existing guidance and displays patient-specific recommendations.
Proposed Weighting:	High
Rationale:	Cervical cancer is largely a disease of health inequity, with higher rates among lower socio-economic groups, immigrant populations, and women in rural settings.[22] Cervical cancer is highly preventable when precancerous lesions are detected early and appropriately managed.[53] However, the complexity of and frequent updates to existing evidence-based clinical guidelines make it challenging for clinicians to stay abreast of the latest recommendations.[53] In addition, limited availability of and accessibility to CDS make it difficult for groups who are medically underserved to receive screening and/or appropriate follow-up care. The CCSM CDS is one solution to help improve cervical cancer outcomes. The CCSM CDS provides clinical guidelines in a shareable, structured, and computer-interpretable format to facilitate meaningful improvements in the number of patients screened and treated for cervical precancer. This includes addressing current gaps in screening uptake and timely follow-up care among populations that are often medically underserved.[22] Analysis of data collected from 1,037 Federally Qualified Health Centers from 2016 to 2021 by the Health Resources and Services Administration (HRSA) Uniform Data System (UDS) found that only about 50 percent of women received recommended cervical cancer screening.[16] Additionally, National Quality Assurance Committee (NCQA) Healthcare Effectiveness and Data Information Set (HEDIS) measures of cervical cancer screening rates show that Medicaid HMOs have rates at least 10% lower than Commercial HMOs.[42] The CDC-developed CCSM CDS tool has been developed in a standards-based, EHR-agnostic way.[21,44] The CDS tools are designed to help clinicians more efficiently evaluate patient clinical data against CCSM guidance and display patient-specific recommendations. This reduces the manual workload of monitoring patients who need screening and potential follow-up. Evidence suggests that clinician adherence to the CCSM guidelines can assist clinicians in improving screening and management outcomes and address existing disparities in guideline concordant care.[46] This activity will leverage the convenience and efficiency of more sophisticated, standards-based decision support tooling to assist clinicians in applying complex data-driven guidelines.[21] This CCDS CDS can help provide optimal care and better

	engagement with diverse patient populations, including historically underserved populations.[22,53,16,42] We propose weighting this activity high, because this activity will require integrating the CCSM CDS tool into clinicians'/practices' EHR dashboards, learning how to use it, and then using it. See the definition of high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Behavioral/Mental Health and Substance Use Screening & Referral for Pregnant and Postpartum Women
Proposed Activity Description:	Screen for perinatal mood and anxiety disorders (PMADs) and substance use disorder (SUD) in pregnant and postpartum women, and screen and refer to treatment and/or refer to appropriate social services, and document this in-patient care plans.
Proposed Weighting:	High
Rationale:	As many as one in five women are affected by perinatal mood and anxiety disorders (PMADs) in their lifetimes [23,24]yet studies estimate that between 50-80 percent of women are not screened during the prenatal or postpartum periods.[6] This highlights barriers to receiving behavioral healthcare in the perinatal period, such as stigma in receiving mental health care, lack of awareness about the prevalence of PMADs, and limited access to affordable behavioral health services.[51] Though all women can experience PMADs, those that are particularly vulnerable include historically underserved racial and ethnic populations, those with lower socioeconomic status, and younger mothers.[51] Research has demonstrated a link between untreated PMADs and maternal SUD[3,33,39,43] While there are limited data estimating the prevalence of maternal SUD, opioid use among perinatal women quadrupled between 1998 and 2014, leading to an increase in infants born with Neonatal Abstinence Syndrome (NAS)[2,3]. Methamphetamine and marijuana use among pregnant and postpartum women has also increased.[1,62] The largest disparity in maternal SUD, particularly opioid use disorder, is seen among mothers living in rural areas[61] Increased costs associated with maternal SUD, particularly for infants born with NAS was estimated at approximately $93,400 per infant in 2012.[43] While the effects of untreated PMADs and maternal SUD can lead to increased severity of PMADs (including risk of maternal suicide), initiation or increased substance use behaviors, and pregnancy complications,[5,19] the implications extend beyond mothers. Infants and children can also be impacted by lower rates of mother/infant bonding, breastfeeding, safe sleep and other infant safety practices, and other activities impacting neurodevelopment.[8,51] Infants, children, and partners of mothers who experience PMADs are also more likely to experience a depressive disorder.[35,51] Furthermore, prevalence of maternal substance use disorders is associated with increased number of children entering the foster system and increased risk of substance use among these children.[51,54] Rates of screening for PMADs and maternal SUD greatly vary during pregnancy and postpartum.[6] The American College of Obstetricians and Gynecologists (ACOG) recommends that all perinatal women be screened for PMADs, and referred for services upon positive screen.[2] The American Academy of Pediatrics recommends that pediatricians routinely screen mothers of patients for postpartum depression at the one-, two-, four- and six-month well child visits.[17] The U.S. Preventive Services Task Force also recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions and has determined that doing so provides improved outcomes for those at increased risk.[4,7]

	There are several prominent guidelines for screening and treating substance use disorder in pregnant women, including the Substance Abuse and Mental Health Services Administration Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and their Infants.[45] The Biden-Harris Administration has also released the National Drug Control Strategy and Substance Use in Pregnancy: Improving Outcomes for Families plan that outlines key steps to "explore, identify barriers, and establish policy to help pregnant women with substance use disorder (SUD) obtain prenatal care and addiction treatment without fear of child removal."[56,57,58,59] Many of these guidelines describe the need for routine verbal screenings to reduce bias and discrimination in those who are screened using specimens.[25] We propose making this activity high-weighted, because MIPS-eligible clinicians will need considerable time and resources to implement the requirements for this activity to train providers on appropriate screening practices, integrate screenings into clinical workflow, and establish a mechanism for referring, linking, and following up with patients upon positive screen. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
Proposed Activity Description:	Complete age-appropriate screening for mental health and substance use in older adults, as well as screening and referral to treatment and/or referral to appropriate social services, and document this in-patient care plans.
Proposed Weighting:	High
Rationale:	Social isolation in the elderly is associated with depression; anxiety; cognitive decline; physical disabilities; lower self-ratings of health; and premature mortality from all causes.[19,26,41,54] Nearly one-quarter (24 percent) of Americans aged 65 and older living in the community are considered to be socially isolated, and a sizable proportion of adults in the US report feeling lonely (35 percent of adults aged 45 and older and 43 percent of adults aged 60 and older).[34] Also, unhealthy alcohol use and use of other drugs has been increasing rapidly among older adults.[37,63] The Substance Abuse and Mental Health Services Administration (SAMHSA), the American Society of Addiction Medicine (ASAM), and the American Psychiatric Association (APA) all recommend routine screening for mental health and substance use issues in elders to identify ongoing concerns or patients at risk for future issues.[39] Many mental health screening tools available for the general adult population, such as the Patient Health Questionnaire (PHQ-9) depression screener and the Generalized Anxiety Disorder 7-item scale (GAD-7), are appropriate for older adults.[38] The APA recommends that "older individuals be referred to treatment settings that offer age-appropriate group therapy and non-confrontational individual therapy focusing on late-life issues of loss and sources of social support. Older adults also deserve to receive full consideration for the potential benefits of medication management for substance use disorders."[4] We propose making this activity high-weighted, because MIPS eligible clinicians will need considerable time and resources to implement the requirements for this activity. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).

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Table B: Changes to Previously Adopted Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

In this rule, we propose to modify one previously finalized improvement activity for the CY 2024 performance period/2026 MIPS payment year and future years.

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_16**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of Decision Support and Standardized Treatment Protocols
Current Activity Description:	Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing to modify this activity's description, "Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs," and its validation criteria to explicitly promote the use of clinical decision support (CDS), particularly open-source, freely available, interoperable CDS. "Moving the needle" to make progress toward interoperability continues to be an essential Federal goal, as demonstrated by new rules that the Office of the National Coordinator for Health Information Technology (ONC) announced on April 11, 2023, that it will be proposing for Cures Act implementation.[1] The urgent importance of interoperability is noted on the HealthIT.gov website: "Interoperability helps clinicians deliver safe, effective, patient-centered care. It also provides new ways for individuals and caregivers to access electronic health information to manage and coordinate care. Advancing interoperability is now an essential part of most health care activities ranging from health equity to public health emergency response."[2]
Proposed Revised Activity Title:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs.
Proposed Revised Activity Description:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools—and standardized treatment protocols to manage workflow on the care team to meet patient needs. Clinicians should focus on utilizing open-source, freely available, interoperable CDS in completing the requirements of this activity.

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TABLE C: Improvement Activities Proposed for Removal for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years

In this rule, we propose to remove three previously finalized improvement activities from the CY 2024 performance period/2026 MIPS payment year and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_BMH_6**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Implementation of co-location PCP and MH services
Current Activity Description:	Integration facilitation and promotion of the colocation of mental health and substance use disorder services in primary and/or non-primary clinical care settings.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor two, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice, and factor three, activity does not align with current clinical guidelines or practice. We have received interested-party feedback expressing concern that this activity is out-of-date, and that IA_BMH_6 substantially overlaps with IA_BMH_7 (Implementation of Integrated Patient Centered Behavioral Health Model). IA_BMH_7 better aligns with evidence supporting improved patient outcomes.[1] Furthermore, IA_BMH_6 focuses on co-location of mental health and substance use disorder services in primary and/or non-primary clinical care settings, which has not been found to consistently improve patient outcomes.[2] In the current rulemaking cycle, we are proposing two new activities in the Behavioral and Mental Health subcategory. We note that the removal of IA_BMH_6 is being proposed in order to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_13**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Obtain or Renew an Approved Waiver for Provision of Buprenorphine as Medication-Assisted Treatment for Opioid Use Disorder
Current Activity Description:	Complete any required training and obtain or renew an approved waiver for provision of medication-assisted treatment of opioid use disorders using buprenorphine. Note: This activity may be selected once for low-capacity waivers, as these do not expire, and once every 3 years for the expanded waiver, in keeping with renewal requirements.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under removal factor three, activity does not align with current clinical guidelines or practice. In late December 2022, the end of the "X-waiver" was announced, so doctors/nurse practitioners no longer need to complete training and obtain a waiver from the Drug Enforcement Administration (DEA) to be able to prescribe buprenorphine (medication-assisted treatment; MAT). Section 1262 of the Consolidated Appropriations Act of 2023 (also referred to as the "Omnibus Bill") was passed in December 2022.[3] We note that the removal of IA_BMH_13 is being proposed in order to ensure that the improvement activities Inventory best reflects current clinical practice, and in no way reflects a de-emphasis of the ongoing priority CMS is placing on behavioral and mental health in general, and on substance use disorder in particular. This removal is necessary as the X-waiver is no longer a requirement of MAT prescribing.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_29**

Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Consulting Appropriate Use Criteria (AUC) Using Clinical Decision Support when Ordering Advanced Diagnostic Imaging
Current Activity Description:	Clinicians attest that they are consulting specified applicable AUC through a qualified clinical decision support mechanism for all applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2018. This activity is for clinicians that are early adopters of the Medicare AUC program (2018 performance year) and for clinicians that begin the Medicare AUC program in future years as specified in our regulation at §414.94. The AUC program is required under section 218 of the Protecting Access to Medicare Act of 2014. Qualified mechanisms will be able to provide a report to the ordering clinician that can be used to assess patterns of image-ordering and improve upon those patterns to ensure that patients are receiving the most appropriate imaging for their individual condition.
Current Weighting:	High
Removal Rationale:	We propose to remove this activity under removal factor seven, improvement activity is "obsolete." The AUC CDS program has ended, so it will no longer be possible to attest to this activity.

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APPENDIX 3: MVP INVENTORY

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix contains two groups of proposed MVP tables: Group A: proposed new MVPs and Group B: proposed modifications to previously finalized MVPs. Group A includes five new proposed MVPs. Group B includes 12 previously finalized MVPs with proposed modifications.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category that are relevant to the clinical theme of the MVP. In addition, each MVP includes a foundational layer that is comprised of population health measures and Promoting Interoperability performance category measures.

MVP Development: Performance Category Sources

The MVP tables below contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures are located in the 2023 MIPS Quality Measures List on the Quality Payment Program website.[460] In addition, see Appendix 1: MIPS Quality Measures of this proposed rule for proposed modifications to existing quality measures.
- Existing QCDR measures are based on the most recent publication of the 2023 QCDR Measure Specification file, located on the Quality Payment Program website.[461] We plan to modify the list of 2024 QCDR measures around December 2023.
- Improvement activities are located in the 2023 Improvement Activities Inventory, and the 2023 MIPS Data Validation Criteria are located in the Quality Payment Program website.[462] In addition, see Appendix 2: Improvement Activities of this proposed rule for any proposed removals, additions, or modifications to existing improvement activities.
- Existing cost measures are located in the 2023 Cost Measures Inventory.[463] In addition, see section IV.A.4.f.(2) of this proposed rule for proposals regarding the cost performance category.
- For further details on the population health measures (attributed to the Quality Performance Category) included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located on the Quality Payment Program website.[464] In addition, see section IV.A.4.f.(4) of this proposed rule for proposals regarding the existing Promoting Interoperability performance category measures.

MVP Development: Global Inclusion of a Quality Measure and an Improvement Activity

- Consistent with the priority to advance health equity throughout various CMS programs, including the Quality Payment Program, we are proposing to include Q487: Screening for Social Drivers of Health in both new and previously finalized MVPs. Health equity supports health for all the people served by our programs by designing, implementing, and operationalizing policies and programs that eliminate avoidable differences in health outcomes experienced by people who are disadvantaged or underserved and providing the care and support that beneficiaries need to thrive (*https://www.cms.gov/pillar/health-equity*). The measure supports the process of collecting drivers of health (DOH) data, which is a foundational step towards defining, addressing, and allocating supportive resources to patients in an impactful manner while supporting the performance of clinicians who choose to submit this measure though it is not required. For further details regarding the basis on which CMS determined Q487: Screening for Social Drivers of Health is appropriate to measure clinician performance as well as how it does so, see 87 FR 69872 through 69784.
- We are proposing to add a newly proposed improvement activity, IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways, a high weighted activity, to each of the new and previously finalized MVPs. This activity would expand the opportunity for quality improvement (QI) activities across and among practices, ultimately leading to improvements in quality of care and fostering a culture of participation by all staff. In addition, we believe this activity would incentivize voluntary MVP adoption, which is important to the transformation of clinical practice by encouraging practice to participate payment options such as MVPs and APMs that measure performance in ways that are more relevant practice members. See Appendix 2, Improvement Activities: Table A of this proposed rule for detailed information regarding the proposed IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways activity.

MVP Table Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables in the Group A and Group B tables below:

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[460] See the 2023 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2217/2023%20MIPS%20Quality%20Measures%20List.xlsx.*

[461] See *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2174/2023_QCDR_Measure_Specifications.xlsx* for QCDR measures.

[462] See the 2023 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2237/2023%20Improvement%20Activities%20Inventory.zip* and 2023 MIPS Data Validation Criteria: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2313/2023%20MIPS%20Data%20Validation%20Criteria.zip* for improvement activity details.

[463] See the 2023 Cost Measures Inventory: *https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2023.*

[464] See the 2023 Promoting Interoperability Measure Specifications: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2223/2023%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip* for Promoting Interoperability measure details.

● New quality measures, improvement activities, and cost measures proposed for inclusion in MIPS beginning with the CY 2024 performance period/2026 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1, MIPS Quality Measures: Table Group A of this proposed rule for further information regarding new MIPS measures. See Appendix 2, Improvement Activities: Table A of this proposed rule for further information regarding new improvement activities. See section IV.A.4.f.(2) of this proposed rule for further information regarding new cost measures.

● Quality measures, improvement activities, and cost measures that we are proposing to add to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

● Existing quality measures and improvement activities with proposed revisions are identified with an asterisk (*).

● Quality measures identified with a double asterisk (**) are individual measures duplicating a component of the TBD: Preventive Care and Wellness (composite) measure. The quality measures that include the (**) can only be submitted when included in an MVP. Please see Appendix 1: MIPS Quality Measures Table A.6 of this proposed rule for any additional information regarding the Preventive Care and Wellness (composite) measure.

● Quality measures that are considered high priority (as defined in § 414.1305) are illustrated with an exclamation point (!) and outcome measures (as defined in § 414.1305) are illustrated with a double exclamation point (!!). Further details of these types of measures are located in the CMS Measures Management System Hub.[465]

● QCDR measures proposed in the MVP tables below that are illustrated with a pound sign (#) indicate that testing data is still pending and due on or before September 1, 2023. We refer readers to the CY 2022 PFS final rule for additional details regarding requirements for QCDR measures considered for an MVP (86 FR 65407 through 65408).

● Improvement activities that include a health equity component are illustrated with a tilde (~) within the MVP table.

● IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation is illustrated with a percent (%) to indicate that attestation to this improvement activity provides full credit for the improvement activity performance category within an MVP.

In addition, quality measure collection types are identified in parentheses after each quality measure title within each MVP table and improvement activity medium/high weight designations are identified in parentheses after each improvement activity.

Group A: New MVPs Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

A.1 Focusing on Women's Health MVP

The proposed Focusing on Women's Health MVP focuses on the clinical theme of providing treatment and management of women's health. This MVP would be most applicable to clinicians who treat patients within the practice of gynecology, obstetrics, and urogynecology, including nonphysician practitioners (NPPs) such as certified nurse-midwives, nurse practitioners, and physician assistants.

Quality Measures

We propose to include 18 MIPS quality measures and one QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of women's health by assessing three critical areas of care: obstetrics, preventive women's health, and urogynecology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in women's health:

- Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: This MIPS quality measure ensures annual assessment for the presence or absence of urinary incontinence for women.
- Q112: Breast Cancer Screening: This MIPS quality measure ensures women have a mammogram to screen for breast cancer in accordance with clinical guidelines.
    - Q309: Cervical Cancer Screening: This MIPS quality measure assesses for the performance of cervical cancer screening in women in accordance with clinical guidelines.
    - Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
    - Q335: Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse): This inverse MIPS quality measure identifies patients who have delivered a live singleton at < 39 weeks of gestation and assesses for elective deliveries (without medical indication) by cesarean birth or induction of labor.
    - Q336: Maternity Care: Postpartum Follow-up and Care Coordination: This MIPS quality measure ensures the following postpartum care is completed: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and assurance immunization are reviewed and updated.
    - Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients: This MIPS quality measure currently requires that patients have received a one-time screening for hepatitis C virus (HCV) infection. However, this measure has proposed substantive changes that would require treatment initiation or referral within a set timeframe in addition to screening. Please reference Appendix 1: MIPS Quality Measures: Table D.45 for further information.
    - Q422: Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury: This MIPS quality measure evaluates patients that undergo cystoscopy at the time of hysterectomy for pelvic organ prolapse to evaluate for lower urinary tract injury.
    - Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair: This MIPS quality measure evaluates for injury, during or within 30 days, to the bladder after surgery for patients that undergoing pelvic organ prolapse repair.
    - Q448: Appropriate Workup Prior to Endometrial Ablation: This MIPS quality measure ensures endometrial sampling or hysteroscopy with biopsy with results documented prior to an endometrial ablation.
    - Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Facto Profile for Osteoporotic Fracture: This MIPS quality measure ensures women receive an order for a dual-energy x-ray absorptiometry (DXA) scan if they exhibit select risk factors for osteoporotic fracture.
    - Q475: HIV Screening: This MIPS quality measure ensures patients receive a one-time test for HIV.
    - TBD: CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument: This proposed MIPS quality measure evaluates pregnant or postpartum patients for a completed cardiovascular disease (CVD) risk assessment utilizing a standard instrument.
    - UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved: This MIPS quality measure ensures patients diagnosed with osteopenia or osteoporosis achieve a serum 25 Hydroxy-Vitamin D result greater than or equal to 30.0 ng/dL.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to clinicians that specialize in women's health. The quality measures below assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: This MIPS quality measure screens patients, aged 18 years and older, for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. If the patient is screened positive for unhealthy alcohol use, then they should receive brief counseling.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 14 improvement activities that reflect actions and processes undertaken by clinicians who specialize in women's health, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients being seen for women's health care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_16: Promote Self-management in Usual Care
- IA_BMH_11: Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
- IA_BMH_XX: Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities
- IA_PM_XX: Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines

Cost Measures

We propose to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of women's health. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in women's health and align with other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those providing obstetric and gynecological care.
- Total Per Capita Cost (TPCC): This MIPS cost measure captures the overall costs of care after establishing a primary care-type relationship. Obstetricians and gynecologists are included in attribution for the TPCC measure.

Currently, there are no applicable episode-based cost measures available but one could be considered for development in the future.

TABLE A.1: Focusing on Women's Health MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Focusing on Women's Health MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(*) Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQMs Specifications) **(*)(**) Q112:** Breast Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q309:** Cervical Cancer Screening (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(!!) Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q336:** Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQMs Specifications) **(*) Q400:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients (Collection Type: MIPS CQMs Specifications) **Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice (Medium) **(^) IA_BMH_XX:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation	**Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

(Collection Type: MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications) **(*)(!) Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQMs Specifications) **(!!) Q432:** Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQMs Specifications) **(*)(!) Q448:** Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQMs Specifications) **(!) Q472:** Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture (Collection Type: eCQM Specifications) **(*) Q475:** HIV Screening (Collection Type: eCQM Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) **(^) TBD:** CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQMs Specifications) **(#)(!!) UREQA8:** Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	**(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **(^) IA_PM_XX:** Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis IIigh Priority Practices Safety Assurance Factors for EIIR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

	Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.2 Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

The proposed Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP focuses on the clinical theme of providing care for patients experiencing some of the most common otolaryngology conditions such as, but not limited to: otologic conditions, chronic rhinosinusitis (CRS), age-related hearing loss (ARHL) and otitis media. This proposed MVP would be most applicable to clinicians who treat patients within the practice of otolaryngology, including NPPs such as audiologists, nurse practitioners, and physician assistants.

Quality Measures

We propose to include eight MIPS quality measures and four QCDR measures within the quality performance category of this MVP, which promote the management and care associated with otolaryngology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with otolaryngology conditions:

- Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis: This MIPS quality measure ensures adults diagnosed with obstructive sleep apnea have an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.
- Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse): This overuse MIPS quality measure assesses for prescribed antibiotics within 10 days after the onset of symptoms for those patients diagnosed with acute viral sinusitis.
- Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): This appropriate use MIPS quality measure ensures patients diagnosed with acute bacterial sinusitis are prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
- Q355: Unplanned Reoperation within the 30 Day Postoperative Period: This MIPS quality measure evaluates for an unplanned reoperation within 30 days of a denominator eligible procedure.
- Q357: Surgical Site Infection (SSI): This MIPS quality measure evaluates for SSI within 30 days of a denominator eligible procedure.
- AAO16: Age-Related Hearing Loss: Comprehensive Audiometric Evaluation: This MIPS quality measure ensures patients aged 60 years and older who have failed a hearing screening and/or who report suspected hearing loss receive, are ordered, or referred for comprehensive audiometric evaluation.
- AAO20: Tympanostomy Tubes: Comprehensive Audiometric Evaluation: This MIPS quality measure ensures pediatric patients diagnosed with otitis media with effusion (OME) receive tympanostomy tube insertion and a comprehensive audiometric evaluation within 6 months prior to tympanostomy tube insertion.
- AAO21: Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months: This MIPS quality measure ensures pediatric patients diagnosed with otitis media with effusion (OME) including chronic serous, mucoid, or nonsuppurative OME of > or = 3 months duration receive an order or referral for comprehensive audiometric evaluation.
- AAO23: Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines: This MIPS quality measure ensures patients 2 years and older with a diagnosis of allergic rhinitis are prescribed or recommended intranasal corticosteroids (INS) or non-sedating oral antihistamines.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to otolaryngology. The quality measures below assess for age specific screenings, and follow-up actions for select measures:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in treating patients with otolaryngology conditions, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes

and improve quality of care patients with otolaryngology conditions. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_15: Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_13: Practice Improvements to Align with OpenNotes Principles
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements

Cost Measures

We propose to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of otolaryngology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in otolaryngology care and aligns with the other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including otolaryngologic care. This aligns with the surgical measures within this MVP, including Q355: Unplanned Reoperation within the 30 Day Postoperative Period and Q357: Surgical Site Infection (SSI).

Currently, there are no applicable episode-based cost measures available, but one could be considered for development in the future.

TABLE A.2: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(**) **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQMs Specifications)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (~) **IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(*)(!) Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) **(!) Q332:** Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (Collection Type: MIPS CQMs Specifications) **(!!) Q355:** Unplanned Reoperation within the 30 Day Postoperative Period (Collection Type: MIPS CQMs Specifications) **(!!) Q357:** Surgical Site Infection (SSI) (Collection Type: MIPS CQMs Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(#)(!) AAO16:** Age-Related Hearing Loss: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **(#) AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **(#) AAO21:** Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (Collection Type: QCDR) **(#) AAO23:** Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines (Collection Type: QCDR)	**IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(^)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional)

	Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.3 Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

The proposed Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP focuses on the clinical theme of promoting quality care for patients suffering from infectious disorders. This proposed MVP would be most applicable to clinicians who treat patients within the practices of infectious disease and immunology, including NPPs such as nurse practitioners and physician assistants.

Quality Measures

We propose to include 14 MIPS quality measures within the quality performance category of this MVP, which focus on a variety of infectious disease conditions that may impact patient health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in the prevention and treatment of infectious disorders within their patient population:

- Q205: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: This MIPS quality measure ensures patients aged 13 years and older with a diagnosis of HIV/AIDS are screened for chlamydia, gonorrhea, and syphilis at least once since the diagnosis of HIV infection.
- Q310: Chlamydia Screening for Women: This MIPS quality measure identifies women that are sexually active to ensure that they have had at least one test for chlamydia.
- Q338: HIV Viral Load Suppression: This MIPS quality measure ensures all patients with a diagnosis of HIV annually achieve a HIV viral load less than 200 copies/mL at last HIV viral load test.
- Q340: HIV Medical Visit Frequency: This MIPS quality measure ensures all patients with a diagnosis of HIV had at least one medical visit in each 6 month period within a 24 month measurement period.
- Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users: This MIPS quality measure ensures all patients that are identified as active injection drug users receive screening for HCV each year.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients: This MIPS quality measure currently requires that patients have received a one-time screening for hepatitis C virus (HCV) infection. However, this measure has proposed substantive changes that would require treatment initiation or referral within a set timeframe in addition to screening. Please reference Appendix 1: MIPS Quality Measures: Table D.45 for further information.
- Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: This MIPS quality measure ensures adult patients with a diagnosis of chronic hepatitis C cirrhosis receive imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once each year.
- Q475: HIV Screening: This MIPS quality measure ensures patients receive a one-time test for HIV.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to infectious disorders. The quality measures below encourage antimicrobial stewardship, medication reconciliation, appropriate immunization receipt and preventive screenings:

- Q065: Appropriate Treatment for Upper Respiratory Infection (URI): This appropriate use MIPS quality measure evaluates that patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) did not receive an antibiotic order.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- Q240: Childhood Immunization Status: This MIPS quality measure ensures children 2 years of age receive four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 14 improvement activities that reflect actions and processes undertaken by clinicians who provide prevention and treatment for infectious disorders to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing infectious disorder care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PM_XX: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- IA_PSPA_23: Completion of CDC Training on Antibiotic Stewardship
- IA_PSPA_32: Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

Cost Measures

We propose to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of infectious disorders. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in treating infectious disorders and aligns with the other measures and activities within this MVP:

- Total Per Capita Cost (TPCC): This MIPS cost measure captures the overall costs of care after establishing a primary care-type relationship. Infectious Disease specialists are included in attribution for the TPCC measure.

Currently, there are no applicable episode-based cost measures applicable to the clinical topics assessed within other components of this MVP, but one could be considered for development in the future.

TABLE A.3: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High)	**Total Per Capita Cost (TPCC)**

(*) Q205: HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis (Collection Type: MIPS CQMs Specifications) **(*) Q240:** Childhood Immunization Status (Collection Type: eCQM Specifications) **(*) Q310:** Chlamydia Screening for Women (Collection Type: eCQM Specifications) **(*)(!!) Q338:** HIV Viral Load Suppression (Collection Type: MIPS CQMs Specifications) **(!) Q340:** HIV Medical Visit Frequency (Collection Type: MIPS CQMs Specifications) **Q387:** Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQMs Specifications) **(*) Q400:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients (Collection Type: MIPS CQMs Specifications) **Q401:** Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQMs Specifications) **(*) Q475:** HIV Screening (Collection Type: eCQM Specifications) **(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(*)Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(^)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities (Medium) **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **(^) IA_PM_XX:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium) **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship (High) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

	Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

A.4 Quality Care in Mental Health and Substance Use Disorders MVP

The proposed Quality Care in Mental Health and Substance Use Disorders MVP focuses on the clinical theme of promoting prevention of and quality care in behavioral health, including mental health and substance use disorders (SUD). This proposed MVP would be most applicable to clinicians who treat patients with mental health and substance use disorders within the practices of mental/behavioral health and psychiatry, including NPPs such as clinical social workers, nurse practitioners, and physician assistants.

Quality Measures

We propose to include 12 MIPS quality measures and 3 QCDR measures within the quality performance category of this MVP, which focus on a variety of behavioral health, including mental health and SUDs that may impact patient health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP would provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with behavioral health, including mental health and SUDs:

- Q009: Anti-Depressant Medication Management: This MIPS quality measure ensures adult patients diagnosed with major depression treated with antidepressant medication remained on an antidepressant medication treatment. There are two performance rates for this measure that evaluate compliance for at least 84 days or 180 days.
- Q305: Initiation and Engagement of Substance Use Disorder Treatment: This MIPS quality measure ensures patients 13 years of age and older with a new SUD episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation.
- Q366: Follow-Up Care for Children Prescribed ADHD Medication (ADD): This MIPS quality measure ensures children 6-12 years of age with a newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) receive appropriate follow-up care.
- Q370: Depression Remission at Twelve Months: This MIPS quality measure assesses adolescent and adult patients diagnosed with major depression or dysthymia for achieved remission in 12 months (+/- 60 days).
- Q382: Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment: This MIPS quality measure ensures pediatric patients with a diagnosis of major depressive disorder (MDD) receive an assessment for suicide risk.
- Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia: This MIPS quality measure assesses an adult patient diagnosed with schizophrenia or schizoaffective disorder prescribed an antipsychotic medication had a Proportion of Days Covered (PDC) of at least 0.8 for their antipsychotic medications.
- Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD): This MIPS quality measure assesses for the continuous treatment (180 days) of pharmacotherapy treatment for adult patients diagnosed with opioid use disorder.
- TBD: Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder: This proposed MIPS quality measure assesses patients diagnosed with mental and/or substance use disorder for maintenance or improvement in functioning at 30 to 180 days after index assessment.
- TBD: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk: This proposed MIPS quality measure ensures adult patients with suicidal ideation, behavior symptoms or increased suicide risk have a suicide safety plan initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
- TBD: Reduction in Suicidal Ideation or Behavior Symptoms: This proposed MIPS quality measure assesses patients diagnosed with mental and/or substance use disorder with suicidal thoughts, behaviors, or risk symptoms for a reduction in suicidal ideation and/or behavior symptoms within 120 days of index assessment of the Columbia-Suicide Severity Rating Scale (C-SSRS).
- MBHR2: Anxiety Response at 6-months: This MIPS quality measure ensures adult patients with an anxiety disorder demonstrate a response to treatment at 6-months (+/- 60 days).
- MBHR7: Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children: This MIPS quality measure ensures patients with a history of a traumatic event and report symptoms consistent with PTSD for at least one month following the traumatic event have a symptom improvement based on a standardized symptom monitor in response to treatment in at least six months.
- MBHR15: Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment: This MIPS quality measure ensures patients are referred for evaluation due to concerns for cognitive changes or difficulties receive a standardized valid assessment of cognition with results documented, including documentation of provider's consideration of relevant cultural-linguistic and demographic factors that may have affected assessment and resulting assessment.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to behavioral health, including mental health and SUDs. The quality measures below address preventive screenings, which support the capture of the patient's voice and safety for patients that are experiencing behavioral health, including mental health and SUD disorders:

- Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for patients who screen positive.

- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 18 improvement activities that reflect actions and processes undertaken by clinicians who provide neurological care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing neurological care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_5: MIPS Eligible Clinician Leadership in Clinical Trials or CBPR
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_12: Use evidence-based decision aids to support shared decision-making.
- IA_BE_16: Promote Self-management in Usual Care
- IA_BE_23: Integration of patient coaching practices between visits
- IA_BMH_2: Tobacco use
- IA_BMH_5: MDD prevention and treatment interventions
- IA_BMH_7: Implementation of Integrated Patient Centered Behavioral Health Model
- IA_BMH_XX: Behavioral/mental health and substance use screening & referral for pregnant and postpartum women
- IA_BMH_XX: Behavioral/mental health and substance use screening & referral for older adults
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities
- IA_PSPA_32: Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

Cost Measures

We propose to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic behavioral health, including mental health and SUDs. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in mental health and SUDs and align with the other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including hospitalizations for mental health conditions and SUDs.
- Depression: This episode-based cost measures evaluates a clinician's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat depression. While interested parties expressed concerns with the inclusion of this measure within this MVP during the 2024 MVP candidate feedback period, this measure is appropriate for use in MIPS for the reasons described in section IV.A.4.f.(2) of this proposed rule.
- Psychoses and Related Conditions: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients who receive inpatient treatment for psychoses or related conditions during the performance period. This acute inpatient medical condition measure includes costs of services that are clinically related to the attributed clinician's role in managing care during each episode, from the clinical event that opens, or "triggers," the episode through 45 days after the trigger. While interested parties expressed concerns with the inclusion of this measure within this MVP during the 2024 MVP candidate feedback period, this measure is appropriate for use in MIPS for the reasons described in section IV.A.4.f.(2) of this proposed rule.

TABLE A.4: Quality Care in Mental Health and Substance Use Disorders MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the Quality Care in Mental Health and Substance Use Disorders MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures

Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
Q009: Anti-Depressant Medication Management (Collection Type: eCQM Specifications) (*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM Specifications) (*) **Q366:** Follow-Up Care for Children Prescribed ADHD Medication (ADD) (Collection Type: eCQM Specifications) (*)(!!) **Q370:** Depression Remission at Twelve Months (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q382:** Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM Specifications) (*)(!!) **Q383:** Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQMs Specifications) (!) **Q468:** Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQMs Specifications) (*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (^)(!!) **TBD:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQMs Specifications) (^) **TBD:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications) (^)(!!) **TBD:** Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQMs Specifications) (#)(!!) **MBHR2:** Anxiety Response at 6-months (Collection Type: QCDR)	(~) **IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (High) (~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (~) **IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR (Medium) (~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) (~) **IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making. (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_23:** Integration of patient coaching practices between visits (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_BMH_5:** MDD prevention and treatment interventions (Medium) (~) **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model (High) (^) **IA_BMH_XX:** Behavioral/mental health and substance use screening & referral for pregnant and postpartum women (High) (^) **IA_BMH_XX:** Behavioral/mental health and substance use screening & referral for older adults (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (^)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High)	**Medicare Spending Per Beneficiary (MSPB) Clinician** (^) **Depression** (^) **Psychoses and Related Conditions**

(#)(!!) **MBHR7:** Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR) (#)(!) **MBHR15:** Consideration of Cultural-Linguistic and Demographic Factors in Cognitive Assessment (Collection Type: QCDR)	(%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities (Medium) **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support (High)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

A.5 Rehabilitative Support for Musculoskeletal Care MVP

The proposed Rehabilitative Support for Musculoskeletal Care MVP focuses on the clinical theme of promoting quality care for patients. This proposed MVP would be most applicable to clinicians and NPPs who specialize in providing rehabilitative support for musculoskeletal care such as chiropractic, physiatry, physical therapy and occupational therapy, as well as nurse practitioners and physician assistants.

Quality Measures

We propose to include 10 MIPS quality measures within the quality performance category of this MVP, which promote rehabilitative support for patients. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in providing rehabilitative support for musculoskeletal care:

- Q217: Functional Status Change for Patients with Knee Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the knee. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM

for reporting of this quality measure.

- Q218: Functional Status Change for Patients with Hip Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the hip. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q219: Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the lower leg, foot or ankle. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q220: Functional Status Change for Patients with Low Back Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the low back. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q221: Functional Status Change for Patients with Shoulder Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the shoulder. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the elbow, wrist or hand. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.
- Q478: Functional Status Change: This MIPS quality measure uses the FOTO Lower Extremity Physical Function (LEPF) PROM to assess for the risk-adjusted change in functional status for patients with functional deficit related to the neck. To allow flexibility, the measure was updated to allow for utilization of a crosswalk, potentially reducing burden for clinicians and their patients who prefer an alternative (legacy) PROM for reporting of this quality measure.

In addition, we are proposing to include the following broadly applicable MIPS quality measures that are relevant to rehabilitative support for musculoskeletal care. The quality measures below address preventive screenings and care plan for falls:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients, aged 18 years and older, for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q155: Falls: Plan of Care: This MIPS quality measure ensures adult patients, with a history of falls, have a plan of care for falls.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the improvement activity inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We propose to include 17 improvement activities that reflect actions and processes undertaken by clinicians who provide rehabilitative support for musculoskeletal care to patients, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients needing rehabilitative support for musculoskeletal care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_6: Provide Education Opportunities for New Clinicians
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BMH_12: Promoting Clinician Well-Being
- IA_BMH_XX: Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_CC_8: Implementation of documentation improvements for practice/process improvements
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_EPA_3: Collection and use of patient experience and satisfaction data on access
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways

- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PSPA_16: Use of decision support and standardized treatment protocols
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

We propose to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of rehabilitative support for musculoskeletal care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2024 MVP candidate feedback period to determine the cost measure to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in rehabilitative support for musculoskeletal care and aligns with the other measures and activities included within this MVP:

- Low Back Pain: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat low back pain. This aligns with Q220: Functional Status Change for Patients with Low Back Impairments.

TABLE A.5: Rehabilitative Support for Musculoskeletal Care MVP

As stated in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Rehabilitative Support for Musculoskeletal Care MVP. We request comment on the measures and activities included in this MVP.

Symbol Key:
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(**) **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q155:** Falls: Plan of Care (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (!!) **Q217**: Functional Status Change for Patients with Knee Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q218:** Functional Status Change for Patients with Hip Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q219:** Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q220:** Functional Status Change for Patients with Low Back Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q221:** Functional Status Change for Patients with Shoulder Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q222:** Functional Status Change for Patients with Elbow, Wrist or Hand Impairments (Collection Type: MIPS CQMs Specifications) (!!) **Q478:** Functional Status Change for Patients with Neck Impairments (Collection Type: MIPS CQMs Specifications) (*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (~) **IA_AHE_6:** Provide Education Opportunities for New Clinicians (High) (~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) (~) **IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (IIigh) **IA_BMH_12:** Promoting Clinician Well-Being (High) (^) **IA_BMH_XX:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults (High) **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) **IA_CC_8:** Implementation of documentation improvements for practice/process improvements (Medium) **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (~) **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access (Medium) (^)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	(^) **Low Back Pain**
Foundational Layer		

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Group B: Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

TABLE B.1: Advancing Cancer Care MVP

Table B.1 represents the measures and activities that were finalized within the Advancing Cancer Care MVP in (87 FR 70653 through 70659) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Advancing Cancer Care MVP within the quality performance category of this MVP to include three additional MIPS quality measures and one additional QCDR measure that address appropriate cancer care treatment. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians providing cancer care to patients:

- Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors: This MIPS quality measure identifies patients diagnosed with cancer who are on immune checkpoint inhibitor therapy and develop grade 2 or above diarrhea and/or colitis to assess for appropriate intervention of managing immune-related diarrhea and colitis.
- PIMSH13: Oncology: Mutation testing for stage IV lung cancer completed prior to start of targeted therapy: This QCDR measure assesses the use of mutation testing for all actionable biomarkers with appropriate mutation-directed therapy, in accordance with current National Comprehensive Cancer Network (NCCN) guidelines for stage IV non-small cell lung cancer.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add the following broadly applicable MIPS quality measure, which is relevant to patients receiving cancer care and their understanding of their health care treatment journey:

- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in their ability to manage their health and be an active partner in their health care journey.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add six additional improvement activities that address maintenance requests from the public, and that address priority areas including clinician well-being, interoperability, patient safety, and expanding use of telehealth:

- IA_BMH_12: Promoting Clinician Well-Being
- IA_CC_13: Practice Improvements to Align with OpenNotes Principles
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan
- IA_PSPA_13: Participation in Joint Commission Evaluation Initiative
- IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal	**Total Per Capita Cost (TPCC)**

(*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q143**: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (!) **Q144:** Oncology: Medical and Radiation – Plan of Care for Pain (Collection Type: MIPS CQMs Specifications) (!) **Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) (!) **Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQMs Specifications) **Q451:** RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQMs Specifications) (!) **Q452:** Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies (Collection Type: MIPS CQMs Specifications) (!) **Q453:** Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQMs Specifications) (!!) **Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQMs Specifications) **Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (+) **Q490:** Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) (!) **PIMSH2:** Oncology: Utilization of GCSF in Metastatic Colorectal Cancer (Collection Type: QCDR) (+)(#)(!) **PIMSH13:** Oncology: Mutation testing for stage IV lung cancer completed prior to start of targeted therapy (Collection Type: QCDR)	(Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) (+) **IA_BMH_12:** Promoting Clinician Well-Being (High) **IA_CC_1**: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop (Medium) (+) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) **IA_CC_17:** Patient Navigator Program (High) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (+)(~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (+) **IA_ERP_4:** Implementation of a Personal Protective Equipment (PPE) Plan (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) (+) **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	

	(+) IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.2: Optimal Care for Kidney Health MVP

Table B.2 represents the measures and activities that were finalized within the Optimal Care for Kidney Health MVP in (87 FR 70660 through 70664) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Optimal Care for Kidney Health MVP within the quality performance category of this MVP to include to include six additional MIPS quality measures that encompass the appropriate care for kidney health and assess appropriate inclusion on the transplant waitlist. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP encompass appropriate care for kidney health and assess appropriate inclusion on the transplant waitlist:

- Q488: Kidney Health Evaluation: This MIPS quality measure ensures patients with diabetes receive a kidney health evaluation including both an estimated glomerular filtration rate (eGFR) and a urine albumin-creatinine ratio (uACR).
- TBD: First Year Standardized Waitlist Ratio (FYSWR): This proposed MIPS quality measure ensures patients with end-stage renal disease (ESRD) are placed on the kidney or kidney-pancreas transplant list or that the patient received a living donor transplant in the first year after initiation of dialysis.
- TBD: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW): This proposed MIPS quality measure captures the adjusted count of patient months for dialysis patients on the kidney and kidney-pancreas transplant waitlist and patients on the kidney or kidney -pancreas transplant waitlist in active status.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add the following two broadly applicable MIPS quality measures which address patient's understanding of their health care journey:

- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We are also proposing to modify the previously finalized Optimal Care for Kidney Health MVP to remove two MIPS quality measures that would be replaced by MIPS quality measure Q493 Adult Immunization Status, which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for this at-risk patient population. The quality actions represented in the below measures would be captured in the composite measure:

- Q110: Preventive Care and Screening: Influenza Immunization
- Q111: Pneumococcal Vaccination Status for Older Adults

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add two additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity and population health:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients

We are also proposing to remove the following improvement activity in response to maintenance requested from the public and interested-party feedback and agree with the recommendation that IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients better targets the MVP population while still advancing care coordination:

- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component

Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*)(!!) **Q001:** Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (!) **Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*)(!!) **Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (!!) **Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (+)(*) **Q488:** Kidney Health Evaluation (Collection Type: MIPS CQMs Specifications) **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQMs Specifications) (*)(+) **Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) (^)(+) **TBD:** First Year Standardized Waitlist Ratio (FYSWR) (Collection Type: MIPS CQMs Specifications) (^)(+) **TBD:** Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (+)(~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_CC_2**: Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs (Medium) (+) **IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	**Acute Kidney Injury Requiring New Inpatient Dialysis (AKI)** **Total Per Capita Cost (TPCC)**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.3: Optimal Care for Patients with Episodic Neurological Conditions MVP

Table B.3 represents the measures and activities that were finalized within the Optimal Care for Patients with Episodic Neurological Conditions MVP in (87 FR 70665 through 70668) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP within the quality performance category of this MVP to include to include two additional MIPS quality measures that address health equity and the patient's understanding of their health care journey. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add the following broadly applicable MIPS quality measure, which is relevant to patients receiving care for episodic neurological conditions. The quality measure below addresses the patient's understanding of their health care journey:

- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We are also proposing to modify the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP to remove one QCDR measure as it is a process measure with no follow-up or link to a health outcome as doesn't ensure preventive therapies were successful.

- AAN30: Migraine Preventive Therapy Management

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add one additional improvement activity that addresses a maintenance request from the public and that addresses the priority area of including the patient voice in their health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQMs Specifications) **(!) Q419:** Overuse of Imaging for the Evaluation of Primary Headache (Collection Type: MIPS CQMs	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **AAN5:** Medication Prescribed for Acute Migraine Attack (Collection Type: QCDR) (!!) **AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **AAN29:** Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy (Collection Type: QCDR) **AAN31**: Acute Treatment Prescribed for Cluster Headache (Collection Type: QCDR) **AAN32:** Preventive Treatment Prescribed for Cluster Headache (Collection Type: QCDR)	**IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting

	Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.4: Supportive Care for Neurodegenerative Conditions MVP

Table B.4 represents the measures and activities that were finalized within the Supportive Care for Neurodegenerative Conditions MVP in (87 FR 70669 through 70672) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Supportive Care for Neurodegenerative Conditions MVP within the quality performance category of this MVP to include to include one additional MIPS quality measure that addresses health equity. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add one additional improvement activity that addresses a maintenance request from the public, and that addresses the priority area of including patient voices in their health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM Specifications) **Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **(!) Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **(!) Q288:** Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQMs Specifications) **Q290:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (Collection Type: MIPS CQMs	**(~) IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_16:** Promote Self-management in Usual Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BMH_4:** Depression screening (Medium) **IA_BMH_8:** Electronic Health Record Enhancements for BH data capture (Medium) **IA_CC_1:** Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

Specifications) **(*) Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(!) Q293:** Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQMs Specifications) **(*)(!) Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **AAN9:** Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease (Collection Type: QCDR) **(!!) AAN22:** Quality of Life Outcome for Patients with Neurologic Conditions (Collection Type: QCDR) **(!!) AAN34:** Patient reported falls and plan of care (Collection Type: QCDR)	**(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(~) IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PM_21:** Advance Care Planning (Medium) **IA_PSPA_21:** Implementation of fall screening and assessment programs (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Table B.5: Advancing Care for Heart Disease MVP

Table B.5 represents the measures and activities that were finalized within the Advancing Care for Heart Disease MVP in (87 FR 70679 through 70683) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Advancing Care for Heart Disease MVP within the quality performance category of this MVP to include four additional MIPS quality that are relevant to patients receiving care for heart disease. We reviewed the quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP are relevant to patients receiving care for heart disease. The quality measures below address appropriate medications for patients with coronary artery disease (CAD):

- Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy: This MIPS quality measure assesses that patients diagnosed with CAD are prescribed aspirin or clopidogrel.
- Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%): This MIPS quality measure assesses that patients diagnosed with CAD, in addition to a prior myocardial infarction or current or prior LVEF ≤ 40%, are prescribed a beta-blocker therapy.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to add one additional broadly applicable MIPS quality measure that is relevant to patients receiving care for heart disease. The quality measure below addresses the patient's understanding of their health care journey:

- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add two additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity and the incorporation of patient voices into health care decision making:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings

Cost Measures

We are also proposing to add two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of cardiac care. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in cardiac care and align with the other measures and activities included within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including cardiac care. An interested party recommended that the MSPB Clinician measure replace the TPCC measure. We agree that it is appropriate to include MSPB Clinician within this MVP. However, TPCC is appropriate to include in this MVP for the reasons stated when the measure was initially finalized for use in this MVP (86 FR 66012 through 66103).
- Heart Failure: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat heart failure. The addition of this measure aligns with included quality measures, such as Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) and Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority

Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*) Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(+)(*) Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQMs Specifications) **(*) Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*) Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(+)(*) Q118:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker–(ARB)–Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (Collection Type: MIPS CQMs Specifications) **(**) Q128:** Preventive care and screening: Body Mass Index (BMI) screening and follow-up plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use of evidence-based tools to support shared decision making (Medium) **IA_BE_15:** Engagement of Patients, Families, and Caregivers in Developing a Plan of Care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients (Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium)	**Elective Outpatient Percutaneous Coronary Intervention (PCI)** **ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)** **(^)(+) Heart Failure** **(+) Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

(Collection Type: MIPS CQMs Specifications) **(!) Q377:** Functional Status Assessments for Heart Failure (Collection Type: eCQM Specifications) **(!!) Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQMs Specifications) **(!!) Q393:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQMs Specifications) **(!!) Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) **(!!) Q492:** Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (Collection Type: Administrative Claims) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)		

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional)

	Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

Table B.6: Advancing Rheumatology Patient Care MVP

Table B.6 represents the measures and activities that were finalized within the Advancing Rheumatology Patient Care MVP in (87 FR 70687 through 70689) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Advancing Rheumatology Patient Care MVP within the quality performance category of this MVP to include three additional MIPS quality measures and one QCDR measure that are relevant to patients receiving rheumatology care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following QCDR measure proposed within this MVP addresses appropriate clinical care for patients with rheumatological conditions:

- UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function: This QCDR outcome measure ensures assessment of disease control or improvement based on Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score in patients with ankylosing spondylitis.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity. In addition, we are proposing to include two additional broadly applicable MIPS quality measures that are relevant to patients receiving care for rheumatological conditions. The quality measures below address immunization status and the patient's understanding of their health care journey:

- Q493: Adult Immunization Status: This MIPS quality measure ensures that adults are up-to-date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
- TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This proposed MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the ability to manage their health and be an active partner in their health care journey.

We are also proposing to modify the previously finalized Optimal Care for Kidney Health MVP to remove one MIPS quality measure that would be replaced by MIPS quality measure Q493: Adult Immunization Status, which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease for this at-risk patient population. The quality actions represented in the below measure would be captured in the composite measure:

- Q111: Pneumococcal Vaccination Status for Older Adults

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add three additional improvement activities that address maintenance requests from the public, and that address priority areas including incorporating the patient voice into health care decision making:

- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_24: Financial Navigation Program
- IA_BE_25: Drug Cost Transparency

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!) Q130: Documentation of Current Medications in the Medical Record (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High)	**Total Per Capita Cost (TPCC)**

(*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **Q176:** Tuberculosis Screening Prior to First Course Biologic Therapy (Collection Type: MIPS CQMs Specifications) **Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQMs Specifications) **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQMs Specifications) **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (*)(+) **Q493:** Adult Immunization Status (Collection Type: MIPS CQMs Specifications) (^)(+)(!!) **TBD:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQMs Specifications) **ACR12:** Disease Activity Measurements for Patients with PsA (Collection Type: QCDR) (!!) **ACR14:** Gout Serum Urate Target (Collection Type: QCDR) (!) **ACR15:** Safe Hydroxychloroquine Dosing (Collection Type: QCDR) (+)(#)(!!) **UREQA10:** Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	(~) **IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) (+) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) (+) **IA_BE_24:** Financial Navigation Program (Medium) (+) **IA_BE_25**: Drug Cost Transparency (High) **IA_BMH_2:** Tobacco use (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (~) **IA_EPA_2:** Use of telehealth services that expand practice access (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (Medium) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information

	OR Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.7: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Table B.7 represents the measures and activities that were finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP in (87 FR 70690 through 70692) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to include three additional MIPS quality measures and one QCDR measure that are relevant to patients receiving emergency medical care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP address appropriate use of medication and diagnostic testing:

- Q065: Appropriate Treatment for Upper Respiratory Infection (URI): This appropriate use MIPS quality measure evaluates that patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) did not receive an antibiotic order.
- Q416: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years: This appropriate use MIPS quality measure evaluates the appropriate use of head computed tomography (CT) in pediatric patients presenting with minor blunt head trauma.
- HCPR24: Appropriate Utilization of Vancomycin for Cellulitis: This appropriate use QCDR measure evaluates for appropriate antibiotic ordering for patients diagnosed with cellulitis.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

We are also proposing to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to remove one QCDR measure as it is a process measure that should be a standard of care as demonstrated by the measure's high performance in the PY2023 MIPS Historical Quality Benchmarks file.

- ACEP21: Coagulation Studies in Patients Presenting with Chest Pain with No Coagulopathy or Bleeding

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add one additional improvement activity that addresses a maintenance request from the public, and that addresses the priority area of clinician well-being:

- IA_BMH_12: Promoting Clinician Well-Being

We are also proposing to remove the following improvement activities after consideration of feedback received from the public through the MVP maintenance process:

- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

In addition, we are proposing to add one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of emergency medicine. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in emergency medicine and aligns with the other measures and activities included within this MVP:

- Emergency Medicine: This episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients who have an emergency department (ED) visit during the performance period. This measure includes costs of Part A and B services during each episode from the start of the ED visit that opens, or "triggers," the episode through 14 days after the trigger, excluding a defined list of services for each ED visit type that are unrelated to the ED care.

We are also proposing to remove the following cost measure because the Emergency Medicine episode-based cost measure more closely aligns with the measures and activities included in this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component

Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(+)(*) **Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQMs Specifications) (*) **Q254:** Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain (Collection Type: MIPS CQMs Specifications) (!) **Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) (*)(!) **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQMs Specifications) (!) **Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQMs Specifications) (+)(!) **Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (!!) **ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR) (!) **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (Collection Type: QCDR) (!) **ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR) (+)(#)(!) **HCPR24:** Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	(~) **IA_AIIE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) (+) **IA_BMH_12:** Promoting Clinician Well-Being (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_15:** Implementation of Antimicrobial Stewardship Program (ASP) (Medium)	(^)(+) **Emergency Medicine**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)

(!!) Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.8: Improving Care for Lower Extremity Joint Repair MVP

Table B.8 represents the measures and activities that were finalized within the Improving Care for Lower Extremity Joint Repair MVP in (87 FR 70693 through 70695) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Improving Care for Lower Extremity Joint Repair MVP to include one additional MIPS quality measure that is relevant to patients receiving care for lower extremity joint repair. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Double asterisk (**): quality measures that are proposed for submission only when included in an MVP
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(*)(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQMs Specifications) **(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQMs Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM Specifications) **(*)(!!) Q470:** Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_15:** PSH Care Coordination (High) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**

(TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**(%) IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium) **IA_PSPA_27:** Invasive Procedure or Surgery Anticoagulation Medication Management (Medium)	
Foundational Layer		
Population Health Measures		**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation	

TABLE B.9: Patient Safety and Support of Positive Experiences with Anesthesia MVP

Table B.9 represents the measures and activities that were finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP in (87 FR 70695 through 70697) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to include one additional MIPS quality measure and two additional QCDR measures that are relevant to patients receiving anesthesia care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

The following QCDR measures proposed within this MVP address appropriate utilization of general anesthesia and rates of intraoperative hypotension:

- ABG44: Low Flow Inhalational General Anesthesia: This QCDR measure identifies adult patients undergoing elective procedures, lasting at minimum 30 minutes, that require inhalational general anesthesia to assess for appropriate total fresh gas flow during the maintenance phase of the anesthetic.
- EPREOP31: Intraoperative Hypotension among Non-Emergent Noncardiac Surgical Cases: This outcome QCDR measure identifies adult patients undergoing noncardiac, non-emergency surgery requiring general, neuraxial, or regional anesthesia care to evaluate if the patient had a mean arterial pressure (MAP) below 65 mmHg exceeding a cumulative length of 15 minutes.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

We are also proposing to modify the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP to remove one QCDR measure as it is a process measure that should be a standard of care as demonstrated by the measure's high performance in the PY2023 MIPS Historical Quality Benchmarks file.

- AQI69: Intraoperative Antibiotic Redosing

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!!) **Q404:** Anesthesiology Smoking Abstinence (Collection Type: MIPS CQMs Specifications) (!!) **Q424:** Perioperative Temperature Management (Collection Type: MIPS CQMs Specifications) (!) **Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQMs Specifications)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_15:** PSH Care Coordination (High)	**Medicare Spending Per Beneficiary (MSPB) Clinician**

(!) **Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQMs Specifications) (!) **Q477:** Multimodal Pain Management (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (+)(#)(!) **ABG44:** Low Flow Inhalational General Anesthesia (Collection Type: QCDR) (!!) **AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR) (+)(#)(!) **EPREOP31:** Intraoperative Hypotension among Non-Emergent Noncardiac Surgical Cases (Collection Type: QCDR)	**IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Records (High) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange **OR** Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.10: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Table B.10 represents the measures and activities that were finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP in (87 FR 70698 through 70700) with modifications proposed for the CY 2024 performance period/2026 MIPS payment year and future years.

Quality Measures

We are proposing to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP within the quality performance category of this MVP to include to include one additional MIPS quality measure that addresses health equity. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

For the reasons stated in the introduction of this appendix, we are proposing to add a broadly applicable MIPS quality measure, Q487: Screening for Social Drivers of Health, which addresses health equity.

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add three additional improvement activities that address maintenance requests from the public, and that address priority areas including food insecurity, incorporating patient voices into health care decision making, and behavioral and mental health:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BMH_XX: Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new proposed MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category
Pound sign (#): QCDR measures proposed in this MVP table pending testing data

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications) **(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQMs Specifications)	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_24:** Financial Navigation Program (Medium) **(^)(+) IA_BMH_XX:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults (High)	**Intracranial Hemorrhage or Cerebral Infarction**

(*)(!!) Q409: Clinical Outcome Post Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) **(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications) **(+)(*)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)	**IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_17:** Patient Navigator Program (High) **(^)(+)(%) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

TABLE B.11: Value in Primary Care MVP

We are proposing to modify the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled Value in Primary Care MVP. Table B.11 represents the measures and activities that were finalized within the Promoting Wellness MVP (87 FR 70673 through 70678) and the Optimizing Chronic Disease Management MVP (87 FR 70684 through 70686) with modifications proposed for the CY 2024 performance

period/2026 MIPS payment year and future years. This MVP also aligns with the Adult Universal Core Set/Patient Care First CMMI Model primary care measures.

Quality Measures

We are proposing to modify the previously finalized Promoting Wellness MVP to include six additional MIPS quality measures that are relevant to patients receiving primary or preventive care. The quality measures below address appropriate clinical care for patients receiving primary or preventive care including well visits or condition specific visits in the auspices of primary care:

- Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): This inverse outcome MIPS quality measure assesses diabetic patients for poor control of their HbA1c.
- Q236: Controlling High Blood Pressure: This outcome MIPS quality measure assesses patient diagnosed with hypertension for adequately controlled blood pressure.
- Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: This MIPS quality measure ensures patients 13 years of age and older with a new substance use disorder (SUD) episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation.
- Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: This MIPS quality measure identifies patients at high risk of cardiovascular events and ensures they are prescribed or currently on a statin therapy.
- TBD: Preventive Care and Wellness (composite): This composite MIPS quality measure combines 7 current preventive care measures with age and sex appropriate preventive screenings and wellness services, creating a robust, broadly encompassing preventive care assessment. The measure would set a more stringent performance standard by requiring a comprehensive set of preventive care standards be completed for each patient, working to drive quality care, and ensuring more all-inclusive preventive care.
- TBD: Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk: This proposed MIPS quality measure ensures adult patients with suicidal ideation, behavior symptoms or increased suicide risk have a suicide safety plan initiated, reviewed, and/or updated in collaboration between the patient and their clinician.

We are proposing to modify the previously finalized Promoting Wellness MVP to include two additional broadly applicable MIPS quality measures that are relevant to patients receiving primary or preventive care. The quality measures below address health equity, immunization status, and the patient's wishes:

- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker for patients aged 65 years and older.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

We are also proposing to modify the previously finalized Promoting Wellness MVP to remove four MIPS quality measures that would be replaced by MIPS quality measure TBD: Preventive Care and Wellness (composite), which is a more robust measure supporting the comprehensive evaluation of compliance with recommended adult preventive care, improving quality care and preventing/controlling disease for the general patient population. The quality actions represented in the measures below would be captured in the composite measure:

- Q112: Breast Cancer Screening
- Q113: Colorectal Cancer Screening
- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Additionally, the following five measures are being proposed for removal to streamline the clinical concepts within the Value in Primary Care MVP to align with the clinical concepts of preventive care, quality chronic disease management, and alignment with the Adult Universal Foundation measures.[466] The below MIPS quality measures represent important preventive screening and patient voice measures clinical concepts and as such, the measure or concept can be found in other MVPs:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age
- Q309: Cervical Cancer Screening
- Q310: Chlamydia Screening in Women
- Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients
- Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Improvement Activities

For the reasons stated in the introduction of this appendix, we are proposing to add IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways to this MVP. In addition, we are proposing to add three additional improvement

[466] D.B. Jacobs, M. Schreiber, M. Seshamani, D. Tsai, E. Fowler, L.A. Fleisher. Aligning quality measures across CMS—The universal foundation: N Engl J Med (2023).

activities that address maintenance requests from the public, and that address priority areas including equity, food insecurity, and clinical decision support (CDS):

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_PM_XX: Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines
- IA_PM_XX: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services

We are also proposing to remove the following two improvement activities in response to interested-party feedback:

- IA_BMH_9: Unhealthy Alcohol Use for Patients with Co-occurring Conditions of Mental Health and Substance Abuse and Ambulatory Care Patients
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Cost Measures

We propose to add four MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of cardiac care. The additional cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in cardiac care and align with the other measures and activities included within this MVP:

- Asthma/COPD: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat asthma or COPD.
- Diabetes: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat diabetes.
- Depression: This episode-based cost measures evaluates a clinician's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat depression.
- Heart Failure: This episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat heart failure.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Carat symbol (^): when applicable, new MIPS quality measures, improvement activities, and cost measures
Single asterisk (*): existing quality measures and improvement activities with proposed revisions
Single exclamation point (!): quality measures that are considered high priority
Double exclamation point (!!): outcome measures
Tilde (~): improvement activities that include a health equity component
Percent (%): indication that attestation to IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation provides full credit for the improvement activity performance category

Quality	Improvement Activities	Cost
(+)(*)(!!) **Q001:** Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+) **Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (*) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+)(*)(!!) **Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (+)(!) **Q305:** Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (Collection Type: eCQM Specifications) (!) **Q321:** CAHPS for MIPS Clinician/Group	(~) **IA_AHE_3:** Promote Use of Patient-Reported Outcome Tools (High) (+)(~) **IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium) (~) **IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health (High) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium)	(+) **Asthma/COPD** (+) **Diabetes** (^)(+) **Depression** (^)(+) **Heart Failure** **Total Per Capita Cost (TPCC)**

Survey (Collection Type: CAHPS Survey Vendor) (+)(*) **Q438:** Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications) (*) **Q475:** HIV Screening (Collection Type: eCQM Specifications) (!!) **Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQMs Specifications) (+)(*)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications) (*)**Q493**: Adult Immunization Status (Collection Type: MIPS CQMs Specifications) (^)(+) **TBD:** Preventive Care and Wellness (composite) (Collection Type: MIPS CQMs Specifications) (+)(!) **TBD:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQMs Specifications)	**IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) (~) **IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) (^)(+)(%) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways (High) (%) **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation (~) **IA_PM_11:** Regular review practices in place on targeted patient population needs (Medium) **IA_PM_13:** Chronic Care and Preventative Care Management for Empaneled Patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) (^)(+) **IA_PM_XX:** Use of Decision Support to Improve Adherence to Cervical Cancer Screening and Management Guidelines (Medium) (^)(+) **IA_PM_XX**: Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services (Medium)	
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Eligible Clinician Groups (Collection Type: Administrative Claims) (!!) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information **OR** Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT	

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413, 488, et al.

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2024; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413, 488, and 489

[CMS–1779–F]

RIN 0938–AV02

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2024

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates payment rates, including implementing the second phase of the Patient Driven Payment Model (PDPM) parity adjustment recalibration. This final rule also updates the diagnosis code mappings used under PDPM, the SNF Quality Reporting Program (QRP), and the SNF Value-Based Purchasing (VBP) Program. We are also eliminating the requirement for facilities to actively waive their right to a hearing in writing, treating as a constructive waiver when the facility does not submit a request for hearing.

DATES: These regulations are effective October 1, 2023, except for the amendments to §§ 411.15 and 489.20 in instructions 2 and 11, which are effective January 1, 2024.

FOR FURTHER INFORMATION CONTACT: *PDPM@cms.hhs.gov* for issues related to the SNF PPS.

Heidi Magladry, (410) 786–6034, for information related to the skilled nursing facility quality reporting program.

Alexandre Laberge, (410) 786–8625, for information related to the skilled nursing facility value-based purchasing program.

Lorelei Kahn, (443) 803–8643, for information related to the Civil Money Penalties Waiver of Hearing.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index home page, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Burwell at (410) 786–7816.

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I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for fiscal year (FY) 2024, as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication of certain specified information relating to the payment update (see section II.C. of the FY 2024 SNF PPS proposed rule) in the **Federal Register** before the August 1 that precedes the start of each FY. In addition, this final rule includes requirements for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) for the FY 2025 and FY 2026 program years. This final rule will add two new measures to the SNF QRP, remove three measures from the SNF QRP, and modify one measure in the SNF QRP. This final rule will also make policy changes to the SNF QRP, and begin public reporting of four measures. In addition, this final rule includes a summary of comments received in response to our request for information on principles we will use to select and prioritize SNF QRP quality measures in future years and on the update on our health equity efforts. Finally, this final rule includes requirements for the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program, including adopting new quality measures for the SNF VBP Program, finalizing several updates to the Program's scoring methodology, including a Health Equity Adjustment, and finalizing new processes to validate SNF VBP data. We are also changing the current long-term care (LTC) facility requirements that will simplify and streamline the current requirements and thereby increase provider flexibility and reduce unnecessary administrative burden, while also allowing facilities to focus on providing healthcare to

residents to meet their needs. This proposal was previously proposed and published in the July 18, 2019 **Federal Register** in the proposed rule entitled, ''Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency'' (84 FR 34718). We are finalizing this revision for a facility to waive its hearing rights and receive a reduction in civil money penalties. This change to the current LTC requirements will simplify and streamline the current requirements and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing facilities to focus on providing high-quality healthcare to their residents.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, the Federal rates in this final rule update the annual rates that we published in the SNF PPS final rule for FY 2023 (87 FR 47502, August 3, 2022). In addition, this final rule includes a forecast error adjustment for FY 2024 and includes the second phase of the PDPM parity adjustment recalibration. This final rule also updates the diagnosis code mappings used under the PDPM.

Beginning with the FY 2025 SNF QRP, we are modifying the COVID–19 Vaccination Coverage among Healthcare Personnel measure, adopting the Discharge Function Score measure, and removing the (1) Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure, (2) the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients measure, and (3) the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients measure. Beginning with the FY 2026 SNF QRP, we are adopting the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure. We are also changing the SNF QRP data completion thresholds for the Minimum Data Set (MDS) data items beginning with the FY 2026 SNF QRP and making certain revisions to regulation text at § 413.360. This final rule also contains updates pertaining to the public reporting of the (1) Transfer of Health Information to the Patient-Post-Acute Care (PAC) measure, (2) the Transfer of Health Information to the Provider-PAC measure, (3) the Discharge Function Score measure, and (4) the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure. In addition, we summarize comments received in response to the Request for Information (RFI) on principles for selecting and prioritizing SNF QRP quality measures and concepts and the update on our continued efforts to close the health equity gap, including under the SNF QRP.

We are finalizing several updates for the SNF VBP Program. We are adopting a Health Equity Adjustment that rewards top tier performing SNFs that serve higher proportions of SNF residents with dual eligibility status, effective with the FY 2027 program year and adopting a variable payback percentage to maintain an estimated payback percentage for all SNFs of no less than 60 percent. We are adopting four new quality measures to the SNF VBP Program, one taking effect beginning with the FY 2026 program year and three taking effect beginning with the FY 2027 program year. We are also refining the Skilled Nursing Facility 30-Day Potentially Preventable Readmission (SNFPPR) measure specifications and updating the name to the Skilled Nursing Facility Within-Stay Potentially Preventable Readmission (SNF WS PPR) measure effective with the FY 2028 program year. We are adopting new processes to validate SNF VBP program data.

In addition, we are finalizing our proposal to eliminate the requirement for facilities facing a civil money penalty to actively waive their right to a hearing in writing in order to receive a penalty reduction. We are creating, in its place, a constructive waiver process that will operate by default when CMS has not received a timely request for a hearing. The accompanying 35 percent penalty reduction will remain. This will streamline and reduce the administrative burden for CMS, and result in lower administrative costs for most LTC facilities facing civil money penalties (CMPs). The accompanying 35 percent penalty reduction will remain for now, although we plan to revisit this in a future rulemaking. The move to a constructive waiver process in this rule purely reflects the need to reduce costs and paperwork burden for CMS in order to prioritize current limited Survey and Certification resources for enforcement actions, and we continue to consider whether the existing penalty reduction is appropriate given this final policy. The operational change finalized here will streamline and reduce the administrative burden for CMS.

C. Summary of Cost and Benefits

TABLE 1—COST AND BENEFITS

Provision description	Total transfers/costs
FY 2024 SNF PPS payment rate update	The overall economic impact of this final rule is an estimated increase of $1.4 billion in aggregate payments to SNFs during FY 2024.
FY 2025 SNF QRP changes	The overall economic impact of this final rule to SNFs is an estimated benefit of $1,037,261 to SNFs during FY 2025.
FY 2026 SNF QRP changes	The overall economic impact of this final rule to SNFs is an estimated increase in aggregate cost from FY 2025 of $778,591.
FY 2024 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $184.85 million in aggregate payments to SNFs during FY 2024.
FY 2026 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $196.50 million in aggregate payments to SNFs during FY 2026.
FY 2027 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $166.86 million in aggregate payments to SNFs during FY 2027.
FY 2028 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $170.98 million in aggregate payments to SNFs during FY 2028.
FY 2024 Enforcement Provisions for LTC Facilities Requirements Changes.	The overall impact of this regulatory change is an estimated administrative cost savings of $2,299,716 to LTC facilities and $772,044 to the Federal Government during FY 2024.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their digital health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) to facilitate collaboration with interested parties to develop Health Level Seven International® (HL7) Fast Healthcare Interoperability Resource® (FHIR) standards. These standards could support the exchange and reuse of patient assessment data derived from the post-acute care (PAC) setting assessment tools, such as the minimum data set (MDS), inpatient rehabilitation facility -patient assessment instrument (IRF–PAI), Long-Term Care Hospital (LTCH) continuity assessment record and evaluation (CARE) Data Set (LCDS), outcome and assessment information set (OASIS), and other sources.[1] [2] The PACIO Project has focused on HL7 FHIR implementation guides for: functional status, cognitive status and new use cases on advance directives, re-assessment timepoints, and Speech, language, swallowing, cognitive communication and hearing (SPLASCH) pathology.[3] We encourage PAC provider and health IT vendor participation as the efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as a resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED).[4] The DEL furthers CMS' goal of data standardization and interoperability. Standards in the DEL can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2023 ISA is available at *https://www.healthit.gov/sites/isa/files/inline-files/2023%20Reference%20Edition_ISA_508.pdf.*

We are also working with ONC to advance the United States Core Data for Interoperability (USCDI), a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.[5] We are collaborating with ONC and other Federal agencies to define and prioritize additional data standardization needs and develop consensus on recommendations for future versions of the USCDI. We are also directly collaborating with ONC to build requirements to support data standardization and alignment with requirements for quality measurement. ONC has launched the USCDI+ initiative to support the identification and establishment of domain specific datasets that build on the core USCDI foundation.[6] The USCDI+ quality measurement domain currently being developed aims to support defining additional data specifications for quality measurement that harmonize, where possible, with other Federal agency data needs and inform supplemental standards necessary to support quality measurement, including the needs of programs supporting quality measurement for long-term and post-acute care.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) required HHS and ONC to take steps to promote adoption and use of electronic health record (EHR) technology. Specifically, section 4003(b) of the Cures Act required ONC to take steps to advance interoperability through the development of a Trusted Exchange Framework and Common Agreement aimed at establishing full network-to network exchange of health information nationally. On January 18, 2022, ONC announced a significant milestone by releasing the Trusted Exchange Framework [7] and Common Agreement Version 1.[8] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement is a contract that advances those principles. The Common Agreement and the Qualified Health Information Network Technical Framework Version 1 (incorporated by reference into the Common Agreement) establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other, all under commonly agreed to terms. The technical and policy architecture of how exchange occurs under the Common Agreement follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, healthcare practices, hospitals, public health agencies, and Individual Access Services (IAS) Providers.[9] On February 13, 2023, HHS marked a new milestone during an event at HHS headquarters,[10] which recognized the first set of applicants accepted for onboarding to the Common Agreement as Qualified Health Information Networks (QHINs). QHINs will be entities that will connect directly to each other to serve as the core for nationwide interoperability.[11] For more information, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

[1] HL7 FHIR Release 4. Available at *https://www.hl7.org/fhir/.*

[2] HL7 FHIR. PACIO Functional Status Implementation Guide. Available at *https://paciowg.github.io/functional-status-ig/.*

[3] PACIO Project. Available at *http://pacioproject.org/about/.*

[4] Centers for Medicare & Medicaid Services. Newsroom. Fact sheet: CMS Data Element Library Fact Sheet. June 21, 2018. Available at *https://www.cms.gov/newsroom/fact-sheets/cms-data-element-library-fact-sheet.*

[5] USCDI. Available at *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[6] USCDI+. Available at *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[7] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (Jan. 2022). Available at *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[8] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022). Available at *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[9] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[10] ''Building TEFCA,'' Micky Tripathi and Mariann Yeager, Health IT Buzz Blog. February 13, 2023. *https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/building-tefca.*

[11] The Common Agreement defines a QHIN as ''to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

We invite providers to learn more about these important developments and how they are likely to affect SNFs.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33, enacted August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers virtually all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(c)(4) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185, enacted October 6, 2014) amended section 1888(e)(6) of the Act, which requires the Secretary to implement a QRP for SNFs under which SNFs report data on measures and resident assessment data. Finally, section 111 of the Consolidated Appropriations Act, 2021 (CAA, 2021) amended section 1888(h) of the Act, authorizing the Secretary to apply up to nine additional measures to the VBP program for SNFs.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and (e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the Federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full Federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted Federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2023 (87 FR 47502, August 3, 2022).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** the following:

- The unadjusted Federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this final rule provides the required annual updates to the per diem payment rates for SNFs for FY 2024.

III. Analysis and Responses to Public Comments on the FY 2024 SNF PPS Proposed Rule

In response to the publication of the FY 2024 SNF PPS proposed rule, we received 81 public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2024 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general, observations on the SNF PPS and SNF care generally. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters raised concerns with therapy treatment under PDPM, specifically reductions in the amount of therapy furnished to SNF patients since PDPM was implemented. Some of these commenters stated that CMS should revise the existing limit on concurrent and group therapy to provide a financial penalty in cases where the facility exceeds this limit. These commenters also recommended that CMS direct its review contractors to examine the practices of facilities that changed their therapy service provision after PDPM was implemented. Additionally, commenters want CMS to release the results of any monitoring efforts around therapy provision. Finally, several commenters recommended that CMS reinstate a more frequent assessment schedule to discourage gaming.

Response: We appreciate commenters raising these concerns around therapy provision under PDPM, as compared the RUG–IV. We agree with commenters that the amount of therapy that is furnished to patients under PDPM is less than that delivered under RUG–IV. As we stated in the FY 2020 SNF PPS final rule, we believe that close, real-time monitoring is essential to identifying any adverse trends under PDPM. While we have identified the same reduction in therapy services and therapy staff, we believe that these findings must be considered within the context of patient outcomes. To the extent that facilities are able to maintain or improve patient outcomes, we believe that this supersedes changes in service provision, whether this be in the amount of therapy furnished or the mode in which it is furnished. We continue to monitor all aspects of PDPM and advise our review contractors on any adverse trends.

With regard to implementing a specific penalty for exceeding the group and concurrent therapy threshold, based on our current data, we have not identified any widespread misuse of this limit. Should we identify such misuse, either at a provider-level or at

a broader level, we will pursue an appropriate course of action.

Finally, with regard to the recommendation that we reinstate something akin to the assessment schedule that was in effect under RUG–IV, given that PDPM does not reimburse on the basis of therapy minutes, we do not believe that such an increase in administrative burden on providers would have an impact on therapy provision. That being said, we strongly encourage interested parties to continue to provide suggestions on how to ensure that SNF patients receive the care they need based on their unique characteristics and goals.

Comment: One commenter stated that CMS should undertake an analysis of the impact of waiving the 3-day stay requirement during the PHE as compared to the impact on patient cost and outcomes once the requirement has been reinstated. This commenter requests that CMS release the results of such an analysis.

Response: We appreciate this suggestion. We have previously conducted analyses of the associated cost of removing the 3-day stay requirement and found that it would significantly increase Medicare outlays. We have not yet been able to perform such an analysis which would compare the impact of waiving this requirement during the PHE to the impact of it being re-implemented, but we believe it would likely lead to the same result.

Comment: One commenter requested that we consider including recreational therapy time provided to SNF residents by recreational therapists into the case-mix adjusted therapy component of PDPM, rather than having it be considered part of the nursing component. This commenter further suggested that CMS begin collecting data, as part of a demonstration project, on the utilization of recreational therapy, as a distinct and separate service, and its impact on patient care cost and quality.

Response: We appreciate the commenter raising this issue, but we do not believe there is sufficient evidence at this time regarding the efficacy of recreational therapy interventions or, more notably, data which would substantiate a determination of the effect on payment of such interventions, as such services were not considered separately, as were physical, occupational and speech-language pathology services, when the PDPM was being developed. That being said, we would note that Medicare Part A originally paid for institutional care in various provider settings, including SNF, on a reasonable cost basis, but now makes payment using PPS methodologies, such as the SNF PPS. To the extent that one of these SNFs furnished recreational therapy to its inpatients under the previous, reasonable cost methodology, the cost of the services would have been included in the base payments when SNF PPS payment rates were derived. Under the PPS methodology, Part A makes a comprehensive payment for the bundled package of items and services that the facility furnishes during the course of a Medicare-covered stay. This package encompasses nearly all services that the beneficiary receives during the course of the stay—including any medically necessary recreational therapy—and payment for such services is included within the facility's comprehensive SNF PPS payment for the covered Part A stay itself. With regard to developing a demonstration project focused on this particular service, we do not believe that creating such a project would substantially improve the accuracy of the SNF PPS payment rates. Moreover, in light of comments discussed above on the impact of PDPM implementation on therapy provision more generally, we believe that carving out recreational therapy as a separate discipline will not have a significant impact on access to recreational therapy services for SNF patients.

Comment: One commenter raised concerns regarding the perceived lack of adequate financial reporting and cost report auditing. This commenter stated that CMS does not do enough to ensure that the funds paid to providers under the SNF PPS are used appropriately for patient care. Further, this commenter suggested that CMS impose penalties for inaccurate, incomplete and fraudulent SNF ownership and cost data. Finally, this commenter urged CMS to establish a medical-loss ratio for SNFs to ensure that Medicare funds are used for patient care.

Response: We appreciate the commenter raising these concerns. With regard to the need for regulation and penalties associated with incomplete and fraudulent ownership and cost data, we would contend that there are consequences for providers when they are found to have incomplete cost reports or if the data they are reporting to CMS is found to be fraudulent. That being said, we focus on patient outcomes as the basis for assessing if the care provided to SNF patients is appropriate, as well as the Medicare funding used as the basis for that care. Ultimately, it is the responsibility of each SNF provider to ensure that the care provided to their patients, using the funds provided under the SNF PPS, is appropriate and sufficient to meet the unique needs, goals and characteristics of each patient. We encourage interested parties to provide future recommendations and suggestions for how to use SNF cost reports and other data sources to improve CMS auditing and enforcement activities.

IV. SNF PPS Rate Setting Methodology and FY 2024 Update

A. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem Federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the Federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the Federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket, and then standardized for geographic variations in wages and for the costs of facility differences in case-mix. In compiling the database used to compute the Federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the Federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas and adjusted the portion of the Federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

B. SNF Market Basket Update

1. SNF Market Basket

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket that encompasses the most commonly used

cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we rebased and revised the SNF market basket, which included updating the base year from FY 2010 to 2014. In the SNF PPS final rule for FY 2022 (86 FR 42444 through 42463), we rebased and revised the SNF market basket, which included updating the base year from 2014 to 2018.

The SNF market basket is used to compute the market basket percentage increase that is used to update the SNF Federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage increase is adjusted by a forecast error adjustment, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section IV.B.4. of this final rule.

As outlined in the proposed rule, we proposed a FY 2024 SNF market basket percentage increase of 2.7 percent based on IHS Global Inc.'s (IGI's) fourth quarter 2022 forecast of the 2018-based SNF market basket (before application of the forecast error adjustment and productivity adjustment). We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket and/or the productivity adjustment), we would use such data, if appropriate, to determine the FY 2024 SNF market basket percentage increase, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the SNF PPS final rule.

Since the proposed rule, we have updated the FY 2024 market basket percentage increase based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023. The FY 2024 growth rate of the 2018-based SNF market basket is estimated to be 3.0 percent.

2. Market Basket Update Factor for FY 2024

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage increase as the percentage change in the SNF market basket from the midpoint of the previous FY to the midpoint of the current FY. For the Federal rates outlined in this final rule, we use the percentage change in the SNF market basket to compute the update factor for FY 2024. This factor is based on the FY 2024 percentage increase in the 2018-based SNF market basket reflecting routine, ancillary, and capital-related expenses. Sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(B)(i) of the Act require that the update factor used to establish the FY 2024 unadjusted Federal rates be at a level equal to the SNF market basket percentage increase. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2022 through September 30, 2023 to the average market basket level for the period of October 1, 2023 through September 30, 2024. As outlined in the proposed rule, we proposed a FY 2024 SNF market basket percentage increase of 2.7 percent. For this final rule, based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023, the FY 2024 growth rate of the 2018-based SNF market basket is estimated to be 3.0 percent.

As further explained in section IV.B.3. of this final rule, as applicable, we adjust the percentage increase by the forecast error adjustment from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage increase in the market basket exceeds a 0.5 percentage point threshold in absolute terms. Additionally, section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage increase by the productivity adjustment (the 10-year moving average of changes in annual economy-wide private nonfarm business total factor productivity (TFP) for the period ending September 30, 2024) which is estimated to be 0.2 percentage point, as described in section IV.B.4. of this final rule.

We also note that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act (the market basket increase). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket percentage change being less than zero for a fiscal year and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

3. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004 and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2022 (the most recently available FY for which there is final data), the forecasted or estimated increase in the SNF market basket was 2.7 percent, and the actual increase for FY 2022 is 6.3 percent, resulting in the actual increase being 3.6 percentage points higher than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket exceeds the 0.5 percentage point threshold, under the policy previously described (comparing the forecasted and actual market basket percentage increase), the FY 2024 market basket percentage increase of 3.0 percent would be adjusted upward to account for the forecast error adjustment of 3.6 percentage points, resulting in a SNF market basket percentage increase of 6.6 percent, which is then reduced by the productivity adjustment of 0.2 percentage point, discussed in section IV.B.4. of this final rule. This results in a SNF market basket update for FY 2024 of 6.4 percent.

Table 2 shows the forecasted and actual market basket increases for FY 2022.

TABLE 2—DIFFERENCE BETWEEN THE ACTUAL AND FORECASTED MARKET BASKET INCREASES FOR FY 2022

Index	Forecasted FY 2022 increase *	Actual FY 2022 increase **	FY 2022 difference
SNF	2.7	6.3	3.6

* Published in **Federal Register**; based on second quarter 2021 IGI forecast (2018-based SNF market basket).
** Based on the second quarter 2023 IGI forecast (2018-based SNF market basket).

4. Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period).

The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measure of productivity for the U.S. We note that previously the productivity measure referenced at section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term MFP with TFP. BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. We refer readers to the BLS website at *www.bls.gov* for the BLS historical published TFP data. A complete description of the TFP projection methodology is available on our website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch*. In addition, in the FY 2022 SNF final rule (86 FR 42429) we noted that, effective with FY 2022 and forward, we changed the name of this adjustment to refer to it as the ''productivity adjustment,'' rather than the ''MFP adjustment.''

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the productivity adjustment may result in the market basket percentage being less than zero for a FY and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year. Thus, if the application of the productivity adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in a productivity-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted Federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

Based on the data available for the FY 2024 SNF PPS proposed rule, the proposed productivity adjustment (the 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending September 30, 2024) was projected to be 0.2 percentage point. We note that, as we typically do, we have updated our data between the FY 2024 SNF PPS proposed rule and this final rule. Based on IGI's second quarter 2023 forecast, the estimated 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending September 30, 2024 is estimated to be 0.2 percentage point.

Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), and as discussed previously in section IV.B.1. of this final rule, the market basket percentage for FY 2024 for the SNF PPS is based on IGI's second quarter 2023 forecast of the SNF market basket percentage increase, which is estimated to be 3.0 percent. This market basket update is then increased by 3.6 percentage points, due to application of the forecast error adjustment discussed earlier in section IV.B.3. of this final rule. Finally, as discussed earlier in section IV.B.4. of this final rule, we are applying a 0.2 percentage point productivity adjustment to the FY 2024 SNF market basket percentage increase. Therefore, the resulting productivity-adjusted FY 2024 SNF market basket update is equal to 6.4 percent, which reflects a market basket percentage increase of 3.0 percent, plus the 3.6 percentage points forecast error adjustment, and less the 0.2 percentage point productivity adjustment. Thus, we apply a net SNF market basket update factor of 6.4 percent in our determination of the FY 2024 SNF PPS unadjusted Federal per diem rates.

A discussion of the public comments received on the FY 2024 SNF market basket percentage increase to the SNF PPS rates, along with our responses, can be found below.

Comment: One commenter suggested CMS consider allowing SNFs to use different labor percentages for geographic areas with wage indexes less than or greater than 1, similar to IPPS hospitals. They believe this methodological change would allow for the wage index adjustment to match more closely with the provider's costs.

Response: We continue to believe it is technically appropriate and consistent with our interpretation of the statute to use the market basket cost weights, reflecting the national average of SNF costs, to determine the labor-related share applicable for all SNFs. In addition, our analysis of the 2018 SNF Medicare cost report data used to determine the 2018-based SNF market

basket cost weights, shows that the compensation cost weights for urban (accounting for about 70 percent of freestanding SNF costs) and rural SNFs, in aggregate, are both 60 percent—consistent with the 2018-based SNF market basket compensation cost weight.

Comment: One commenter requested that CMS work with interested parties to explore updates to the SNF market basket methodology, potentially with new proxies or alternative data. One commenter identified a few detailed methodological issues for CMS to consider regarding the SNF market basket.

Response: We welcome commenters' input on the SNF market basket and appreciate the suggestions provided. We will consider them for future rulemaking when we propose to rebase and revise the SNF market basket.

Comment: One commenter appreciated the forecast error adjustments during the last two rulemaking cycles but stated that the current methodology may not capture impacts such as the entirety of the cost changes during times of high healthcare resource utilization (for example, during COVID–19 pandemic). The commenter further noted that applying the forecast error adjustment to future payments does not account for inflation that can alter the time-value of money. The commenter requested that CMS consider ways to evaluate the impact of addressing these potential shortcomings of the forecast error adjustment. One commenter recommended that CMS strongly consider including additional labor and cost data into the market basket updates prospectively, rather than retroactively, to adjust for the market basket projections' inability to accurately project rate increases during high inflation periods. One commenter (MedPAC) noted that CMS is not required by statute to make automatic forecast error corrections and in this instance the forecast error correction results in making a larger payment increase in addition to the statutory increases for FY 2024.

Response: The SNF market basket is a price index that measures the change in price, over time, of the same mix of goods and services purchased in the base period. As noted by the commenter, due to the availability of data and rates being set by CMS on a prospective basis, there is a 2-year lag between the forecast error adjustment and its application to the payment rate. For example, as stated in section IV.B.3. of this final rule, the FY 2024 SNF PPS payment rate update includes an adjustment for the FY 2022 market basket forecast error.

Subsequent to the initial cumulative adjustment implemented in FY 2004, the forecast error adjustment has been based on the forecast error from the most recently available FY for which there is final data, and the difference between the forecasted and actual change in the market basket is applied when the difference exceeds a specified threshold. The forecast error adjustment (when it exceeds the threshold of 0.5 percentage point (in absolute terms)) is intended to adjust for when historical price changes differ substantially from the forecasted price changes in order to appropriately pay providers for services provided, rather than typical minor variances that are inherent in statistical measurements. The forecast error adjustment is specifically defined to only account for errors in price forecasts and would appropriately not take into account differences in non-price factors affecting costs.

Therefore, we disagree with the commenter that the CMS forecast error adjustment is inadequate or that it should reflect other factors (such as changes in utilization due to case mix or other non-price factors or the time value of money). We use the most complete and available data for purposes of determining the market basket forecast, forecast error adjustment, and productivity adjustment as well as the most recent claims data when determining the SNF PPS payment rates. We do not forecast changes in the case-mix index.

Comment: Several commenters supported the net payment update of 3.7 percent reflecting a 2.7 percent market basket update. Numerous commenters also recommended that CMS use the most recently available data when determining the market basket update for the final rule.

Several commenters stated that the proposed 3.7 percent net payment update is inadequate when considering the financial hardship and increased costs many health care providers are facing as a result of the PHE and labor shortages. They recommended that CMS use data that better reflects the input price inflation that SNFs have experienced and are projected to experience in 2024. They believe CMS should reassess market basket data and how it weighs wage and benefits data, as they do not believe the updates to the market basket data reasonably reflect the reality of these associated costs. Similarly, one commenter stated that they believe the 2018-based SNF market basket alone no longer serves as an appropriate price proxy due to the growing expenditures in labor, which has driven a recent disproportionate increase in the labor share portion of the market basket. They recommended that CMS use more recent and supplemental labor cost data to accurately reflect a recent increase of the market basket's labor.

One commenter cited a report stating that the average hourly nursing wage increased over 17 percent from 2019 to 2022 as reported on the Medicare cost reports. They stated that the Medicare market basket update had only increased per-stay payments by less than 6 percent during that same time period. The commenter acknowledged that CMS will refresh the market basket update in the final rule with more recent data but expressed concern that the revised update will still be insufficient relative to input cost inflation as illustrated by the discrepancy between input costs and the market basket update in FY 2022.

Several commenters requested CMS exercise its existing authority or conditional funding opportunities to revise the proposed update to annual rates (either though an updated market basket or other allowable means) to account for the rapid rise of costs.

Response: We recognize the various comments on the proposed net payment update of 3.7 percent. Section 1888(e)(5)(A) of the Act states the Secretary shall establish a skilled nursing facility market basket index that reflects changes over time in the *prices* of an appropriate mix of goods and services included in covered skilled nursing facility services. The 2018-based SNF market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period that would determine change in costs are not measured. For the compensation cost weight in the 2018-based SNF market basket (which includes salaried and contract labor employees), we use the Employment Cost Indexes (ECIs) for wages and salaries and benefits for private industry workers in nursing care facilities to proxy the price increase of SNF labor. The ECI (published by the Bureau of Labor Statistics, or BLS) measures the change in the hourly labor cost to employers, independent of the influence of employment shifts among occupations and industry categories. Therefore, we believe the ECI for private industry workers in nursing care facilities, which only reflects the price

change associated with the labor used to provide SNF care and appropriately does not reflect other factors that might affect labor costs, is an appropriate measure to use in the SNF market basket.

We disagree with the commenter's statement that the 2018-based SNF market basket is not adequately reflecting growing expenditures in labor, which has driven a recent disproportionate increase in the labor share portion of the market basket. Our preliminary analysis of the 2021 Medicare cost report data shows the compensation cost weight for freestanding SNFs is 59.9 percent—relatively unchanged from 2018 with 60.2 percent as increases in the contract labor cost weight were accompanied by decreasing wages and salaries and benefit cost weights. We will continue to analyze more recent freestanding skilled nursing Medicare cost report data to assess whether the SNF market basket should be rebased and revised. Any changes to the SNF market basket will be proposed in future rulemaking.

While the forecasted productivity-adjusted market basket update was 2.4 percent in FY 2020, 2.2 percent in FY 2021, and 2.0 percent in FY 2022, the increases in FY 2023 and FY 2024 reflect additional increases from forecast errors over this period (CMS provided a forecast error adjustment for FY 2021 of 1.5 percentage points in the FY 2023 SNF net payment update and a forecast error adjustment for FY 2022 of 3.6 percentage points, which is being applied to the FY 2024 SNF net payment update in this final rule).

While the average hourly wage for nursing from the reported SNF Medicare cost report data increased roughly 17 percent from 2019 to 2021 (the most complete data available), the hourly wages of nearly all other medical occupational categories, which make up approximately 15 percent of wages and salaries, have not increased by nearly as much. We found that the combined average wage for all other medical occupational categories, weighted by each occupation's percentage of total Adjusted Salaries as indicated on Worksheet S–3, Part V, Column 3 of the Medicare cost report, increased by less than 1 percent over the same time period. The compensation price proxy used in the SNF market basket would reflect trends in all occupations combined, which would partly explain why the ECI for wages and salaries for private industry workers in nursing care facilities has not increased at the pace of nursing wages alone.

As proposed, for this final rule, we are updating the SNF market basket percentage increase to reflect more recent data. Based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023, we are finalizing a 2018-based SNF market basket percentage increase of 3.0 percent which reflects a projected increase in compensation prices of 3.4 percent. This is faster projected price growth compared to the proposed FY 2024 market basket increase of 2.7 percent, which reflected a 3.0 percent compensation price growth. Both of the final FY 2024 increases are faster than the 10-year historical average price growth (2.6 percent for the 2018-based SNF market basket, with compensation prices increasing 2.7 percent).

As noted previously, section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act. Section 1888(e)(5)(A) of the Act does not provide the Secretary with the authority to apply a different update factor to SNF PPS payment rates for FY 2024. Additionally, MedPAC annually conducts an analysis of payment adequacy for SNF providers. In its March 2023 Report to Congress (*https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/*) MedPAC noted the combination of Federal relief policies and the implementation of the new case-mix system resulted in overall improved financial performance for SNFs and recommended a 3 percent reduction to the SNF base payment rates.

Comment: Given that CMS is required by statute to implement a productivity adjustment to the market basket update, several commenters urged CMS to closely monitor the impact of such productivity adjustments and requested that the agency work with Congress to permanently eliminate or offset this reduction to SNF payments. Further, they requested that CMS use its exceptions authority under section 1888(e)(3)(A) of the Act to remove the productivity adjustment for any fiscal year that was covered under PHE determination (that is, 2020 (0.4 percent), 2021 (0.0 percent), 2022 (0.7 percent), and 2023 (0.3 percent)) from the calculation of the market basket for FY 2024 and any year thereafter.

Response: Section 1888(e)(5)(B)(ii) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(xi)(II) of the Act to the SNF PPS market basket increase factor. As required by statute, the FY 2024 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending in FY 2024. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, we are required pursuant to section 1888(e)(5)(B)(ii) of the Act to apply the specific productivity adjustment described here.

Comment: MedPAC commented that while they understand that CMS is required to implement the statutory payment update, the combination of Federal relief policies and the implementation of the new case-mix system resulted in overall improved financial performance for SNFs. Thus, they recommended a 3 percent reduction to the SNF base payment rates.

Response: We thank the commenter for their recommendation. However, we are required to update SNF PPS payments by the market basket percentage increase, as directed by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage increase is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act.

Comment: While many commenters were appreciative of the forecast error adjustment, one commenter noted that the application of the forecast error correction results in making a larger payment increase in addition to the statutory increase for FY 2024, even though the aggregate Medicare margin for SNFs is already high.

Response: As most recently discussed in the FY 2023 SNF PPS final rule (87 FR 47502), forecast error adjustments for the SNF market basket were introduced in the FY 2004 SNF PPS final rule (68 FR 46035), with the intended goal ''to pay the appropriate amount, to the correct provider, for the proper service, at the right time''. We note that since implementation, forecast errors have generally been relatively small and clustered near zero and that for FY 2008 and subsequent years, we increased the threshold at which adjustments are triggered from 0.25 to 0.5 percentage

point. Our intent in raising the threshold was to distinguish typical statistical variances from more major unanticipated impacts and unforeseen disruptions of the economy (such as the recent PHE), or unexpected inflationary patterns (either at lower or higher than anticipated rates).

Comment: One commenter suggested that the forecast error adjustment be adopted and utilized across every CMS payment program.

Response: We appreciate the commenter's suggestion and will share this recommendation with our colleagues in other settings.

5. Unadjusted Federal Per Diem Rates for FY 2024

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), in FY 2020 we implemented a new case-mix classification system to classify SNF patients under the SNF PPS, the PDPM. As discussed in section V.B.1. of that final rule (83 FR 39189), under PDPM, the unadjusted Federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and one of which is a non-case-mix component, as existed under the previous RUG–IV model. We proposed to use the SNF market basket, adjusted as described previously in sections IV.B.1. through IV.B.4. of this final rule, to adjust each per diem component of the Federal rates forward to reflect the change in the average prices for FY 2024 from the average prices for FY 2023. We also proposed to further adjust the rates by a wage index budget neutrality factor, described in section IV.D. of this final rule.

Further, in the past, we used the revised Office of Management and Budget (OMB) delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS proposed and final rules, we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

Tables 3 and 4 reflect the updated unadjusted Federal rates for FY 2024, prior to adjustment for case-mix.

TABLE 3—FY 2024 UNADJUSTED FEDERAL RATE PER DIEM—URBAN

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$70.27	$65.41	$26.23	$122.48	$92.41	$109.69

TABLE 4—FY 2024 UNADJUSTED FEDERAL RATE PER DIEM—RURAL

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$80.10	$73.56	$33.05	$117.03	$88.29	$111.72

C. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the Federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, which took effect beginning October 1, 2019. The previous RUG–IV model classified most patients into a therapy payment group and primarily used the volume of therapy services provided to the patient as the basis for payment classification, thus creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

The PDPM uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS, consistent with the provisions of section 1888(e)(4)(G)(i) of the Act. As discussed in section V.A. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. As we have stated in prior rules, for an MDS to be considered valid for use in determining payment, the MDS assessment should be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.*

Under section 1888(e)(4)(H) of the Act, each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The FY 2024 payment rates set forth in this final rule reflect the use of the PDPM case-mix classification system from October 1, 2023, through September 30, 2024. The case-mix adjusted PDPM payment rates for FY 2024 are listed separately for urban and rural SNFs, in Tables 5 and 6 with corresponding case-mix values.

Given the differences between the previous RUG–IV model and PDPM in terms of patient classification and billing, it was important that the format of Tables 5 and 6 reflect these differences. More specifically, under both RUG–IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim to bill

for covered SNF services. Under RUG–IV, the HIPPS code included the three-character RUG–IV group into which the patient classified, as well as a two-character assessment indicator code that represented the assessment used to generate this code. Under PDPM, while providers still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group ''TA'', then the first character in the patient's HIPPS code would be an A. Similarly, if the patient is classified into the SLP group ''SB'', then the second character in the patient's HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies. Finally, the fifth character represents the assessment used to generate the HIPPS code.

Tables 5 and 6 reflect the PDPM's structure. Accordingly, Column 1 of Tables 5 and 6 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient's HIPPS code would be a ''P.'' Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group.

Tables 5 and 6 do not reflect adjustments which may be made to the SNF PPS rates as a result of the SNF VBP Program, discussed in section VII. of this final rule, or other adjustments, such as the variable per diem adjustment. Further, in the past, we used the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos, 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

In the FY 2023 SNF PPS final rule (87 FR 47502), we finalized a proposal to recalibrate the PDPM parity adjustment over 2 years starting in FY 2023, which means that, for each of the PDPM case-mix adjusted components, we lowered the PDPM parity adjustment factor from 46 percent to 42 percent in FY 2023 and we will further lower the PDPM parity adjustment factor from 42 percent to 38 percent in FY 2024. Following this methodology, which is further described in the FY 2023 SNF PPS final rule (87 FR 47525 through 47534), Tables 5 and 6 incorporate the second phase of the PDPM parity adjustment recalibration.

TABLE 5—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN (INCLUDING THE PARITY ADJUSTMENT RECALIBRATION)

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.45	$101.89	1.41	$92.23	0.64	$16.79	ES3	3.84	$470.32	3.06	$282.77
B	1.61	113.13	1.54	100.73	1.72	45.12	ES2	2.90	355.19	2.39	220.86
C	1.78	125.08	1.60	104.66	2.52	66.10	ES1	2.77	339.27	1.74	160.79
D	1.81	127.19	1.45	94.84	1.38	36.20	HDE2	2.27	278.03	1.26	116.44
E	1.34	94.16	1.33	87.00	2.21	57.97	HDE1	1.88	230.26	0.91	84.09
F	1.52	106.81	1.51	98.77	2.82	73.97	HBC2	2.12	259.66	0.68	62.84
G	1.58	111.03	1.55	101.39	1.93	50.62	HBC1	1.76	215.56	.....	.....
H	1.10	77.30	1.09	71.30	2.7	70.82	LDE2	1.97	241.29	.....	.....
I	1.07	75.19	1.12	73.26	3.34	87.61	LDE1	1.64	200.87	.....	.....
J	1.34	94.16	1.37	89.61	2.83	74.23	LBC2	1.63	199.64	.....	.....
K	1.44	101.19	1.46	95.50	3.5	91.81	LBC1	1.35	165.35	.....	.....
L	1.03	72.38	1.05	68.68	3.98	104.40	CDE2	1.77	216.79	.....	.....
M	1.20	84.32	1.23	80.45	.....	.....	CDE1	1.53	187.39	.....	.....
N	1.40	98.38	1.42	92.88	.....	.....	CBC2	1.47	180.05	.....	.....
O	1.47	103.30	1.47	96.15	.....	.....	CA2	1.03	126.15	.....	.....
P	1.02	71.68	1.03	67.37	.....	.....	CBC1	1.27	155.55	.....	.....
Q	.....	.....	.....	.....	.....	.....	CA1	0.89	109.01	.....	.....
R	.....	.....	.....	.....	.....	.....	BAB2	0.98	120.03	.....	.....
S	.....	.....	.....	.....	.....	.....	BAB1	0.94	115.13	.....	.....
T	.....	.....	.....	.....	.....	.....	PDE2	1.48	181.27	.....	.....
U	.....	.....	.....	.....	.....	.....	PDE1	1.39	170.25	.....	.....
V	.....	.....	.....	.....	.....	.....	PBC2	1.15	140.85	.....	.....
W	.....	.....	.....	.....	.....	.....	PA2	0.67	82.06	.....	.....
X	.....	.....	.....	.....	.....	.....	PBC1	1.07	131.05	.....	.....
Y	.....	.....	.....	.....	.....	.....	PA1	0.62	75.94	.....	.....

TABLE 6—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL (INCLUDING THE PARITY ADJUSTMENT RECALIBRATION)

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.45	$116.15	1.41	$103.72	0.64	$21.15	ES3	3.84	$449.40	3.06	$270.17
B	1.61	128.96	1.54	113.28	1.72	56.85	ES2	2.90	339.39	2.39	211.01
C	1.78	142.58	1.60	117.70	2.52	83.29	ES1	2.77	324.17	1.74	153.62
D	1.81	144.98	1.45	106.66	1.38	45.61	HDE2	2.27	265.66	1.26	111.25
E	1.34	107.33	1.33	97.83	2.21	73.04	HDE1	1.88	220.02	0.91	80.34
F	1.52	121.75	1.51	111.08	2.82	93.20	HBC2	2.12	248.10	0.68	60.04
G	1.58	126.56	1.55	114.02	1.93	63.79	HBC1	1.76	205.97	.....	.....
H	1.10	88.11	1.09	80.18	2.7	89.24	LDE2	1.97	230.55	.....	.....
I	1.07	85.71	1.12	82.39	3.34	110.39	LDE1	1.64	191.93	.....	.....
J	1.34	107.33	1.37	100.78	2.83	93.53	LBC2	1.63	190.76	.....	.....
K	1.44	115.34	1.46	107.40	3.5	115.68	LBC1	1.35	157.99	.....	.....
L	1.03	82.50	1.05	77.24	3.98	131.54	CDE2	1.77	207.14	.....	.....
M	1.20	96.12	1.23	90.48	.....	.....	CDE1	1.53	179.06	.....	.....
N	1.40	112.14	1.42	104.46	.....	.....	CBC2	1.47	172.03	.....	.....
O	1.47	117.75	1.47	108.13	.....	.....	CA2	1.03	120.54	.....	.....
P	1.02	81.70	1.03	75.77	.....	.....	CBC1	1.27	148.63	.....	.....
Q	.....	.....	.....	.....	.....	.....	CA1	0.89	104.16	.....	.....
R	.....	.....	.....	.....	.....	.....	BAB2	0.98	114.69	.....	.....
S	.....	.....	.....	.....	.....	.....	BAB1	0.94	110.01	.....	.....
T	.....	.....	.....	.....	.....	.....	PDE2	1.48	173.20	.....	.....
U	.....	.....	.....	.....	.....	.....	PDE1	1.39	162.67	.....	.....
V	.....	.....	.....	.....	.....	.....	PBC2	1.15	134.58	.....	.....
W	.....	.....	.....	.....	.....	.....	PA2	0.67	78.41	.....	.....
X	.....	.....	.....	.....	.....	.....	PBC1	1.07	125.22	.....	.....
Y	.....	.....	.....	.....	.....	.....	PA1	0.62	72.56	.....	.....

Commenters submitted the following comments related to the proposed Federal per diem rates for FY 2024. A discussion of these comments, along with our responses, appears below.

Comment: One commenter stated that the case-mix adjusted rates for PT, OT, SLP, and nursing categories are higher in urban areas than in rural areas, which exacerbate inequalities between rural and urban SNFs.

Response: We disagree with the commenter's statement that the case-mix adjusted rates for the PT, OT and SLP components are higher in urban than rural areas as shown in Tables 5 and 6. As most recently noted in the FY 2023 SNF PPS final rule (87 FR 47502), the Federal per diem rates were established separately for urban and rural areas using allowable costs from FY 1995 cost reports, and therefore, account for and reflect the relative costs differences between urban and rural facilities. We note that the SNF PPS payment rates are updated annually by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered SNF services and a portion of these rates are further adjusted by a wage index to reflect geographic variations in wages. We will continue to monitor our SNF payment policies to ensure they reflect as accurately as possible the current costs of care in the SNF setting.

Comment: One commenter was appreciative of the increase in payment for FY 2024 and encouraged CMS to maximize support for rural SNFs.

Response: We thank the commenter for their support of the payment rate update for FY 2024 and note that rural SNFs are expected to experience, on average, a 3.3 percent increase in payments compared with FY 2023.

Comment: Commenters encouraged CMS to continue to monitor the impact of the PDPM on beneficiaries' access to appropriate SNF services, including therapy services to address any emerging problems affecting SNF residents.

Response: We thank the commenter for their suggestion. We will continue to monitor the impact of the PDPM implementation on patient outcomes and other metrics to identify any adverse trends accompanying the revisions to the PPS.

Comment: Commenters generally expressed appreciation that the parity adjustment was phased in over 2 years but expressed concern that there would be a reduction to the SNF payment rates for FY 2024 due to this adjustment. A few commenters requested that the PDPM parity adjustment be delayed, reduced, cancelled or be phased in over an additional 2 years. One commenter indicated that they support implementing the remainder of the recalibrated parity adjustment in FY 2024 to prevent continued SNF payments in excess of the intended budget neutral implementation of the PDPM.

Response: We thank the commenters for their support of the phase in of the parity adjustment. We believe the 2-year phase-in was sufficient to mitigate adverse payment impacts while also ensuring that payment rates for all SNFs are set accurately and appropriately. As such, we do not believe it would be appropriate to expand the phase-in period beyond than what was finalized in the FY 2023 SNF PPS final rule. We refer readers to the FY 2023 SNF PPS final rule (87 FR 47502), for a full discussion of the rationale related to the implementation of this policy.

D. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We will continue this practice for FY 2024, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment

serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data under the inpatient prospective payment system (IPPS) also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, without applying the occupational mix, rural floor, or outmigration adjustment, as the basis for the SNF PPS wage index. For FY 2024, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2019 and before October 1, 2020 (FY 2020 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000) gave the Secretary the discretion to establish a geographic reclassification procedure specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. To date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of the data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. Adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors (MACs), potentially far in excess of those required under the IPPS, given that there are nearly five times as many SNFs as there are inpatient hospitals. While we continue to believe that the development of such an audit process could improve SNF cost reports, which is determined to be adequately accurate for cost development purposes, in such a manner as to permit us to establish a SNF-specific wage index, we do not believe this undertaking is feasible.

In addition, we will continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2022 SNF PPS wage index. For rural geographic areas that do not have hospitals and, therefore, lack hospital wage data on which to base an area wage adjustment, we will continue using the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2024, there are no rural geographic areas that do not have hospitals, and thus, this methodology will not be applied. For rural Puerto Rico, we will not apply this methodology due to the distinct economic circumstances there; due to the close proximity of almost all of Puerto Rico's various urban and non-urban areas, this methodology will produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas. Instead, we will continue using the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we will continue using the average wage indexes of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2024, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), after the expiration of this 1-year transition on September 30, 2006, we used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided minor updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013 and were adopted under the SNF PPS in the FY 2017 SNF PPS final rule (81 FR 51983, August 5, 2016). In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300) which was adopted in the SNF PPS final rule for FY 2019 (83 FR 39173, August 8, 2018).

As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) beginning October 1, 2020, including a 1-year transition for FY 2021 under which we applied a 5 percent cap on any decrease in a hospital's wage index compared to its wage index for the prior fiscal year (FY 2020). The updated OMB delineations more accurately reflect the contemporary urban and rural nature of areas across the country, and the use of such delineations allows us to determine more accurately the appropriate wage index and rate tables to apply under the SNF PPS.

In the FY 2023 SNF PPS final rule (87 FR 47521 through 47525), we finalized a policy to apply a permanent 5 percent cap on any decreases to a provider's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. Additionally, we finalized a policy that a new SNF would be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new SNF would not have a wage index in the prior FY. We amended the SNF PPS regulations at 42 CFR 413.337(b)(4)(ii) to reflect this permanent cap on wage index decreases. A full discussion of the adoption of this policy is found in the FY 2023 SNF PPS final rule.

As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR

43423), this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. OMB issued further revised CBSA delineations in OMB Bulletin No. 20–01, on March 6, 2020 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). However, we determined that the changes in OMB Bulletin No. 20–01 do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, we did not propose to adopt the revised OMB delineations identified in OMB Bulletin No. 20 01 for FY 2022 or 2023, and for these reasons we are likewise not making such a requirement for FY 2024. The wage index applicable to FY 2024 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Once calculated, we will apply the wage index adjustment to the labor-related portion of the Federal rate. Each year, we calculate a labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2022 (86 FR 42437), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2018-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. The methodology for calculating the labor-related portion beginning in FY 2022 is discussed in detail in the FY 2022 SNF PPS final rule (86 FR 42461 through 42463).

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2024. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2024 than the base year weights from the SNF market basket. We calculate the labor-related relative importance for FY 2024 in four steps. First, we compute the FY 2024 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2024 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2024 relative importance for each cost category by multiplying this ratio by the base year (2018) weight. Finally, we add the FY 2024 relative importance for each of the labor-related cost categories (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of Capital-Related expenses) to produce the FY 2024 labor-related relative importance.

For the proposed rule, the labor-related share for FY 2024 was based on IGI's fourth quarter 2022 forecast of the 2018-based SNF market basket with historical data through the third quarter of 2022. As outlined in the proposed rule, we noted that if more recent data became available (for example, a more recent estimate of the labor-related share relative importance) we would use such data, if appropriate, for the SNF final rule. For this final rule, we base the labor-related share for FY 2024 on IGI's second quarter 2023 forecast, with historical data through the first quarter of 2023 of the 2018-based SNF market basket.

Table 7 summarizes the labor-related share for FY 2024, based on IGI's second quarter 2023 forecast of the 2018-based SNF market basket, compared to the labor-related share that was used for the FY 2023 SNF PPS final rule.

TABLE 7—LABOR-RELATED SHARE, FY 2023 AND FY 2024

	Relative importance, labor-related share, FY 2023 22:2 forecast [1]	Relative importance, labor-related share, FY 2024 23:2 forecast [2]
Wages and salaries	51.9	52.5
Employee benefits	9.5	9.3
Professional fees: Labor-related	3.5	3.4
Administrative & facilities support services	0.6	0.6
Installation, maintenance & repair services	0.4	0.4
All other: Labor-related services	2.0	2.0
Capital-related (.391)	2.9	2.9
Total	70.8	71.1

[1] Published in the **Federal Register**; Based on the second quarter 2022 IHS Global Inc. forecast of the 2018-based SNF market basket.
[2] Based on the second quarter 2023 IHS Global Inc. forecast of the 2018-based SNF market basket.

To calculate the labor portion of the case-mix adjusted per diem rate, we will multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the FY 2024 labor-related share percentage provided in Table 7. The remaining portion of the rate would be the non-labor portion. Under the previous RUG–IV model, we included tables which provided the case-mix adjusted RUG–IV rates, by RUG–IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, as we discussed in the FY 2020 final rule (84 FR 38738), under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that existed in the prior rulemaking.

Therefore, to aid interested parties in understanding the effect of the wage

index on the calculation of the SNF per diem rate, we have included a hypothetical rate calculation in Table 9.

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2024 (Federal rates effective October 1, 2023), we apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the unadjusted Federal rates by a budget neutrality factor, equal to the ratio of the weighted average wage adjustment factor for FY 2023 to the weighted average wage adjustment factor for FY 2024. For this calculation, we will use the same FY 2022 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor portion of the rate component multiplied by the wage index plus the non-labor portion of the rate component. The finalized budget neutrality factor for FY 2024 is 0.9997.

We note that if more recent data become available (for example, revised wage data), we would use such data, as appropriate, to determine the wage index budget neutrality factor in the SNF PPS final rule.

We solicited public comment on the proposed SNF wage adjustment for FY 2024. The following is a summary of the comments we received and our responses.

Comment: One commenter did not support any increases in the labor-related share as any facility that has a wage index less than 1.0 will suffer financially from a rise in the labor-related share. They stated that across the country, there is a growing disparity between the high-wage and low-wage States.

Response: We appreciate the commenter's concern. However, each year we calculate a labor-related share based on the relative importance of labor-related cost categories, to account historical and projected price changes between the base year and the payment year (FY 2024 in this rule). The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. As shown in Table 7, the slight increase in the labor-related share is due to an increase in the wages and salaries relative importance cost weight, reflecting the faster wage prices compared to other nonwage prices in the SNF market basket. This increase is consistent with comments we have received during this rulemaking about faster wage prices.

As discussed above, based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023, we are finalizing the FY 2024 labor-related share of 71.1 percent based on the relative importance of each of the labor-related cost categories in the 2018-based SNF market basket.

Comment: Commenters stated support of the permanent 5-percent cap on wage index decreases. One commenter encouraged CMS to implement these caps in a non-budget neutral manner to stabilize provider reimbursement and avoid further unexpected reductions for other providers.

Response: We appreciate the commenters' support of the permanent cap on wage index decreases. As for budget neutrality, we do not believe that the permanent 5-percent cap policy for the SNF wage index should be applied in a non-budget-neutral manner. The statute at section 1888(e)(4)(G)(ii) of the Act requires that adjustments for geographic variations in labor costs for a FY are made in a budget-neutral. We refer readers to the FY 2023 SNF PPS final rule (87 FR 47521 through 47523) for a detailed discussion and for responses to these and other comments relating to the wage index cap policy.

Comment: While commenters support the current wage index methodology for FY 2024, including not requiring the commitment of resources needed to do audits on cost reports at this time, others encourage CMS to continue to reform the wage index policies (for example, SNF-specific wage index utilizing SNF audited cost report and nursing wage data).

Response: We appreciate the commenters' support of the proposed wage index policies for FY 2024. In the absence of a SNF-specific wage index, we believe the use of the pre-reclassified and pre-floor hospital wage data (without the occupational mix adjustment) continue to be an appropriate and reasonable proxy for the SNF PPS. For a detailed discussion of the rationale for our current wage index policies and for responses to these recurring comments, we refer readers to the FY 2023 SNF PPS final rule (87 FR 47513 through 47516) and the FY 2016 SNF PPS final rule (80 FR 46401 through 46402).

Comment: One commenter recommended that CMS should, as a matter of policy, require that SNFs provide wages on parity with hospitals for nursing staff. This commenter stated that, given that the SNF wage index is based on hospital wages, CMS should require that SNFs pay the same wages as the hospitals for nursing staff.

Response: We appreciate the commenter's suggestion. While we continue to believe that the pre-reclassified and pre-floor hospital wage index serves as an appropriate proxy for the SNF PPS, we do not believe that it would be appropriate for us to require SNFs to pay a certain amount to their staff. How a SNF chooses to reimburse their staff is a private financial arrangement between the facility and its staff, which means that we believe it would be inappropriate to establish regulations that govern this matter since there is no statutory authority present.

After consideration of public comments, we are finalizing our proposal regarding the wage index adjustment for FY 2024.

E. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section VIII. of this final rule for further discussion of the updates we are finalizing for the SNF VBP Program.

F. Adjusted Rate Computation Example

Tables 8 through 10 provide examples generally illustrating payment calculations during FY 2024 under PDPM for a hypothetical 30-day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 23224), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 8 shows the adjustments made to the Federal per diem rates (prior to application of any adjustments under the SNF VBP Program as discussed previously and taking into account the second phase of the parity adjustment recalibration discussed in section IV.C. of this final rule) to compute the provider's case-mix adjusted per diem rate for FY 2024, based on the patient's PDPM classification, as well as how the variable per diem (VPD) adjustment

factor affects calculation of the per diem rate for a given day of the stay. Table 9 shows the adjustments made to the case-mix adjusted per diem rate from Table 8 to account for the provider's wage index. The wage index used in this example is based on the FY 2024 SNF PPS wage index that appears in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* Finally, Table 10 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 10 also includes the VPD adjustment factors for each day of the patient's stay, to clarify why the patient's per diem rate changes for certain days of the stay. As illustrated in Table 10, SNF XYZ's total PPS payment for this particular patient's stay would equal $21,717.98.

TABLE 8—PDPM CASE-MIX ADJUSTED RATE COMPUTATION EXAMPLE

Per diem rate calculation				
Component	Component group	Component rate	VPD adjustment factor	VPD adj. rate
PT	N	$98.38	1.00	$98.38
OT	N	92.88	1.00	92.88
SLP	H	70.82	1.00	70.82
Nursing	N	180.05	1.00	180.05
NTA	C	160.79	3.00	482.37
Non-Case-Mix		109.69		109.69
Total PDPM Case-Mix Adj. Per Diem				1,034.19

TABLE 9—WAGE INDEX ADJUSTED RATE COMPUTATION EXAMPLE

PDPM wage index adjustment calculation						
HIPPS code	PDPM case-mix adjusted per diem	Labor portion	Wage index	Wage index adjusted rate	Non-labor portion	Total case mix and wage index adj. rate
NHNC1	$1,034.19	$735.31	0.9637	$708.62	$298.88	$1,007.50

TABLE 10—ADJUSTED RATE COMPUTATION EXAMPLE

Day of stay	NTA VPD adjustment factor	PT/OT VPD adjustment factor	Case mix and wage Index adjusted per diem rate
1	3.0	1.0	$1,007.50
2	3.0	1.0	1,007.50
3	3.0	1.0	1,007.50
4	1.0	1.0	694.22
5	1.0	1.0	694.22
6	1.0	1.0	694.22
7	1.0	1.0	694.22
8	1.0	1.0	694.22
9	1.0	1.0	694.22
10	1.0	1.0	694.22
11	1.0	1.0	694.22
12	1.0	1.0	694.22
13	1.0	1.0	694.22
14	1.0	1.0	694.22
15	1.0	1.0	694.22
16	1.0	1.0	694.22
17	1.0	1.0	694.22
18	1.0	1.0	694.22
19	1.0	1.0	694.22
20	1.0	1.0	694.22
21	1.0	0.98	690.49
22	1.0	0.98	690.49
23	1.0	0.98	690.49
24	1.0	0.98	690.49
25	1.0	0.98	690.49
26	1.0	0.98	690.49
27	1.0	0.98	690.49
28	1.0	0.96	686.77
29	1.0	0.96	686.77

TABLE 10—ADJUSTED RATE COMPUTATION EXAMPLE—Continued

Day of stay	NTA VPD adjustment factor	PT/OT VPD adjustment factor	Case mix and wage Index adjusted per diem rate
30	1.0	0.96	686.77
Total Payment			21,717.98

V. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.C. of the FY 2024 SNF PPS proposed rule. This approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, of one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with § 413.345, we include in each update of the Federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. We also designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in 42 CFR 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the initial Medicare assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are correctly assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html* (where such designations appear in the paragraph entitled ''Case Mix Adjustment''), and would publish such designations in rulemaking only to the extent that we actually intend to propose changes in them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*), in the paragraph entitled ''Case Mix Adjustment.''

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that any services prompting the assignment of one of the designated case-mix classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations where the sole classifier that triggers the presumption is itself assigned through the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the initial Medicare assessment.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

Effective with services furnished on or after January 1, 2024, section 4121(a)(4) of the CAA, 2023 added marriage and family therapists and mental health counselors to the list of practitioners at section 1888(e)(2)(A)(ii) of the Act whose services are excluded from the consolidated billing provision. We note that there are no rate adjustments required to the per diem to offset these exclusions, as payments for services made under section 1888(e)(2)(A)(ii) of the Act are not specified under the requirement at section 1888(e)(4)(G)(iii) of the Act as services for which the Secretary must ''provide for an appropriate proportional reduction . . .equal to the aggregate increase in payments attributable to the exclusion''. See section IV.D. of the FY 2024 SNF PPS

proposed rule for a discussion of the proposed regulatory updates implementing this change.

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.* In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA 1999) (Pub. L. 106–113, enacted November 29, 1999) amended section 1888(e)(2)(A)(iii) of the Act by further excluding a number of individual high-cost, low probability services, identified by HCPCS codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA 1999 amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf*.

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA 1999 not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of these four specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA 1999 Conference report (H.R. Conf. Rep. No. 106–479 at 854 (1999)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA 1999 is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of the BBRA 1999 do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA 1999: they must fall within one of the four service categories specified in the BBRA 1999; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA 1999 Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791).

Effective with items and services furnished on or after October 1, 2021, section 134 in Division CC of the CAA, 2021 established an additional category of excluded codes in section 1888(e)(2)(A)(iii)(VI) of the Act, for certain blood clotting factors for the treatment of patients with hemophilia and other bleeding disorders along with items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act. Like the provisions enacted in the BBRA 1999, section 1888(e)(2)(A)(iii)(VI) of the Act gives the Secretary the authority to designate additional items and services for exclusion within the category of items and services related to blood clotting factors, as described in that section. Finally, as noted previously in this final rule, section 4121(a)(4) of Division FF of CAA, 2023 amended section 1888(e)(2)(A)(ii) of the Act to exclude marriage and family therapist services and mental health counselor services from consolidated billing effective January 1, 2024.

In the proposed rule, we specifically solicited public comments identifying HCPCS codes in any of these five service categories (chemotherapy items, chemotherapy administration services, radioisotope services, customized prosthetic devices, and blood clotting factors) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We may consider excluding a particular service if it meets our criteria for exclusion as specified previously. We requested that commenters identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA amendment and the CAA, 2021 identified a set of excluded items and services by means of specifying individual HCPCS codes within the designated categories that were in effect as of a particular date (in the case of the BBRA 1999, July 1, 1999, and in the case of the CAA, 2021, July 1, 2020), as subsequently modified by the Secretary. In addition, as noted in this section of the preamble, the statute (sections 1888(e)(2)(A)(iii)(II) through (VI) of the Act) gives the Secretary authority to identify additional items and services for exclusion within the five specified categories of items and services described in the statute, which are also designated by HCPCS code. Designating the excluded services in this manner makes it possible for us to utilize program issuances as the vehicle for accomplishing routine updates to the excluded codes to reflect any minor revisions that might subsequently occur in the coding system itself, such as the assignment of a different code number to a service already designated as excluded, or the creation of a new code for a type of service that falls within one of the established exclusion categories and meets our criteria for exclusion.

Accordingly, in the event that we identify through the current rulemaking cycle any new services that will actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we will identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, October 1, 2023). By making any new exclusions in this manner, we can similarly accomplish routine future updates of these additional codes through the issuance of program instructions. The latest list of excluded codes can be found on the SNF Consolidated Billing website at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling.*

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS create a new exclusion category that excludes expensive items and services based on a price threshold. Another commenter requested that CMS review the statute and change the statute to provide equal access and payment for DME items for residents in a SNF. Some commenters

suggested that CMS exclude expensive antibiotics. Finally, some commenters requested that CMS add clinical social workers to the SNF exclusion list.

Response: As we noted in the proposed rule, sections 1888(e)(2)(A)(iii)(II) through (VI) of the Act give the Secretary authority to identify additional items and services for exclusion only within the categories of items and services described in the statute. Accordingly, it is beyond the statutory authority of CMS to exclude services that do not fit these categories, or to create additional categories of excluded services. The changes requested by these commenters are beyond the scope of CMS authority and would require Congressional action.

Comment: A commenter requested that CMS add Altuviio, a new class of factor VIII therapy for adults and children with hemophilia A, the list of blood clotting factor exclusions. Altuviio is currently billed using the miscellaneous J code—J 7199, Hemophilia Clotting Factor, not otherwise classified, and has not been assigned its own J code.

Response: As we noted in the proposed rule, we are only able to add services to the exclusion list once they have actually been assigned a HCPCS code. The approach that Congress adopted to identify the individual blood clotting factor drugs being designated for exclusion consisted of listing them by HCPCS code in the statute itself (section 1888(e)(2)(A)(iii)(VI) of the Act). Thus, a blood clotting factor drug's assignment to its own specific code serves as the mechanism of designating it for exclusion, as well as the means by which the claims processing system is able to recognize that exclusion. Accordingly, the assignment of a blood clotting factor drug to its own code is a necessary prerequisite to consider that service for exclusion from consolidated billing under the SNF PPS. We cannot add a miscellaneous non-descriptive code such as J7199. When the code is assigned, we will review it as part of our standard review of new HCPCS codes for exclusion.

Comment: Several commenters named specific suggestions of drugs for exclusion in the chemotherapy category, including: Tecvayli; Denosumab, Leuprolide, and Keytruda; Ponatinib, Gilteritinib, Idhifa, Onureg, Midostaurin, Sprycel, Venetoclax, Promacta, Fulphila, Neulasta, Zarxio, Udenyca; Imatinib, Dasatinib, Nilotinib, Cabozantinib, Sunitinib, and Lenalidomide.

Response: For the reasons discussed previously in this final rule as well as prior rulemaking, the particular drugs cited in these comments remain subject to consolidated billing.

In the case of leuprolide acetate and denosumab, we have addressed these when suggested in past rulemaking cycles, most recently in the SNF PPS final rules for FY 2023 (87 FR 47502, August 3, 2022). In those rules, we explained that these drugs are unlikely to meet the criterion of ''low probability'' specified in the BBRA.

With regard to all other specific drugs mentioned, these are not actually chemotherapy drugs, but rather either immunotherapy or other non-chemotherapy treatments for cancer, or non-chemotherapy services related to or used in conjunction with chemotherapy or in treatment of chemotherapy symptoms. As such, these services do not fit the chemotherapy category or any existing exclusion categories. As we noted in the proposed rule, sections 1888(e)(2)(A)(iii)(II) through (VI) of the Act give the Secretary authority to identify additional items and services for exclusion only within the categories of items and services described in the statute. Accordingly, it is beyond the statutory authority of CMS to exclude services that do not fit these categories, or to create additional categories of excluded services. Such changes would require Congressional action. Additionally, some of these drugs do not have unique HCPCS codes assigned, which as we explained in the preceding comment, is a necessary prerequisite to consider that service for exclusion from consolidated billing under the SNF PPS.

Comment: A commenter noted that CMS website and manual materials contain out of date material with regard to the exclusion of blood clotting factors enacted in the Consolidated Appropriations Act (CAA) of 2021 and implemented by the FY 2022 SNF Final Rule (86 FR 42442).

Response: We appreciate the commenter bringing this to our attention and will update our online materials accordingly.

Comment: One commenter requested a copy of the consolidated billing exclusion list or instructions on how to find it. The statutory language specifying exclusion categories is set out in sections 1888(e)(2)(A)(ii) and (iii) of the Act.

Response: The consolidated billing exclusion list is available online at: *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling.*

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html.*

D. Revisions to the Regulation Text

We proposed to make the following revisions in the regulation text. Section 4121(a)(4) of Division FF of the CAA, 2023 requires Medicare to exclude marriage and family therapist (MFT) services and mental health counselor services (MHC) from SNF consolidated billing for services furnished on or after January 1, 2024. Exclusion from consolidated billing allows these services to be billed separately by the performing clinician rather than being included in the SNF payment. To reflect the recently-enacted exclusion of MFT services and MHC services from SNF consolidated billing at section 1888(e)(2)(A)(ii) of the Act (as discussed in section V.B of the proposed rule), we proposed to redesignate current § 411.15(p)(2)(vi) through (xviii) as § 411.15(p)(2)(viii) through (xx),

respectively. In addition, we proposed to redesignate § 489.20(s)(6) through (18) as § 489.20(s)(8) through (20), respectively. We also proposed to add new regulation text at §§ 411.15(p)(2)(vi) and (vii) and 489.20(s)(6) and (7). Specifically, proposed new §§ 411.15(p)(2)(vi) and 489.20(s)(6) would reflect the exclusion of services performed by an MFT, as defined in section 1861(lll)(2) of the Act. Proposed new §§ 411.15(p)(2)(vii) and 489.20(s)(7) would reflect the exclusion of services performed by an MHC, as defined in section 1861(lll)(4) of the Act.

Subsequently, we identified the need for additional conforming changes to the regulatory text. In addition to adding the two new exclusions themselves to the regulation text as set forth in the proposed rule, the existing exclusion for certain telehealth services will need to be revised as well, because it cross-refers to subparagraphs that are now being renumbered as a result of adding the new exclusions. Specifically, a conforming change is needed in the consolidated billing exclusion provision on telehealth services at existing § 411.15(p)(2)(xii) (which, as a result of the other regulation text changes finalized in this rule, will be redesignated § 411.15(p)(2)(xiv)) and in the parallel provider agreement provision on telehealth services at existing § 489.20(s)(12) (which, as a result of the other regulation text changes finalized in this rule, will be redesignated § 489.20(s)(14)). As these additional conforming edits serve to ensure effective implementation of this new exclusion, and because these new conforming edits additionally serve to expand access to telehealth services, we are confident in making these additional changes in this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters agreed and appreciated the new exclusion of MFT and MHC services. A few commenters stated that, in light of the exclusion of MFT and MHC services, CMS should consider also excluding services furnished by clinical social workers (CSW). One commenter cited a recent nursing home study which recommended that nursing homes should retain more clinical social workers and CMS should allow for Medicare reimbursement for services furnished by these practitioners.

Response: We appreciate the support that we received in relation to the proposed regulatory text changes. With regard to the additional exclusion of CSW services, we would note that unlike the services of certain other types of practitioners (such as physicians and clinical psychologists), CSW services do not appear in the list of services that the law specifies in section 1888(e)(2)(A)(ii) through (iv) of the Act as being excluded from the consolidated billing requirement. Adding CSW services to the statutory list of services that are excluded from SNF consolidated billing would require legislation by Congress to amend the law itself.

In light of the comments received on this issue, we are finalizing the additions as proposed, with the additional conforming edits that we identified during the comment period.

VI. Other SNF PPS Issues

A. Technical Updates to the PDPM ICD–10 Mappings

1. Background

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the Patient Driven Payment Model (PDPM), effective October 1, 2019. The PDPM utilizes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM, hereafter referred to as ICD–10) codes in several ways, including using the patient's primary diagnosis to assign patients to clinical categories under several PDPM components, specifically the PT, OT, SLP, and NTA components. While other ICD–10 codes may be reported as secondary diagnoses and designated as additional comorbidities, the PDPM does not use secondary diagnoses to assign patients to clinical categories. The PDPM ICD–10 code to clinical category mapping, ICD–10 code to SLP comorbidity mapping, and ICD–10 code to NTA comorbidity mapping (hereafter collectively referred to as the PDPM ICD–10 code mappings) are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.*

In the FY 2020 SNF PPS final rule (84 FR 38750), we outlined the process by which we maintain and update the PDPM ICD–10 code mappings, as well as the SNF Grouper software and other such products related to patient classification and billing, to ensure that they reflect the most up to date codes. Beginning with the updates for FY 2020, we apply nonsubstantive changes to the PDPM ICD–10 code mappings through a subregulatory process consisting of posting the updated PDPM ICD–10 code mappings on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.* Such nonsubstantive changes are limited to those specific changes that are necessary to maintain consistency with the most current PDPM ICD–10 code mappings.

On the other hand, substantive changes that go beyond the intention of maintaining consistency with the most current PDPM ICD–10 code mappings, such as changes to the assignment of a code to a clinical category or comorbidity list, would be through notice and comment rulemaking because they are changes that affect policy. We note that, in the case of any diagnoses that are either currently mapped to Return to Provider or that we are finalizing to classify into this category, this is not intended to reflect any judgment on the importance of recognizing and treating these conditions. Rather, we believe that there are more specific or appropriate diagnoses that would better serve as the primary diagnosis for a Part-A covered SNF stay.

2. Clinical Category Changes for New ICD–10 Codes for FY 2023

Each year, we review the clinical category assigned to new ICD–10 diagnosis codes and propose changing the assignment to another clinical category if warranted. This year, we proposed changing the clinical category assignment for the following five new ICD–10 codes that were effective on October 1, 2022:

- D75.84 *Other platelet-activating anti-platelet factor 4 (PF4) disorders* was mapped to the clinical category of Return to Provider. Patients with anti-PF4 disorders have blood clotting disorders. Examples of disorders to be classified with D75.84 are spontaneous heparin-induced thrombocytopenia (without heparin exposure), thrombosis with thrombocytopenia syndrome, and vaccine-induced thrombotic thrombocytopenia. Due to the similarity of this code to other anti-PF4 disorders, we proposed changing the assignment to Medical Management.
- F43.81 *Prolonged grief disorder* and F43.89 *Other reactions to severe stress* were mapped to the clinical category of Medical Management. However, while we believe that SNFs serve an important role in providing services to those beneficiaries suffering from mental illness, the SNF setting is not the setting that would be most beneficial to treat a patient for whom these diagnoses are coded as the patient's primary diagnosis. For this reason, we proposed changing the clinical category of both codes to Return to Provider. We would encourage providers to continue reporting these codes as secondary diagnoses, to ensure that we are able to

identify these patients and that they are receiving appropriate care.

- G90.A *Postural orthostatic tachycardia syndrome (POTS)* was mapped to the clinical category of Acute Neurologic. POTS is a type of orthostatic intolerance that causes the heart to beat faster than normal when transitioning from sitting or lying down to standing up, causing changes in blood pressure, increase in heart rate, and lightheadedness. The treatment for POTS involves hydration, physical therapy, and vasoconstrictor medications, which are also treatments for codes such as E86.0 *Dehydration* and E86.1 *Hypovolemia* that are mapped to the Medical Management category. Since the medical interventions are similar, we proposed changing the assignment for POTS to Medical Management.
- K76.82 *Hepatic encephalopathy* was mapped to the clinical category of Return to Provider. Hepatic encephalopathy is a condition resulting from severe liver disease, where toxins build up in the blood that can affect brain function and lead to a change in medical status. Prior to the development of this code, multiple codes were used to characterize this condition such as K76.6 *Portal hypertension,* K76.7 *Hepatorenal syndrome,* and K76.89 *Other unspecified diseases of liver,* which are mapped to the Medical Management category. Since these codes describe similar liver conditions, we proposed changing the assignment to Medical Management.

We solicited comments on the proposed substantive changes to the PDPM ICD–10 code mappings discussed in this section, as well as comments on additional substantive and nonsubstantive changes that commenters believe are necessary.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they appreciate the ongoing refinements to the PDPM ICD–10 code mappings and the opportunity to provide input to the proposals. Some commenters stated that they would like CMS to identify effective dates on the PDPM website along with educational materials and resources.

Response: We appreciate the positive comments that we received supporting our efforts to map diagnoses more accurately under the PDPM. We also appreciate the suggestion to develop additional educational materials and resources, which we will consider as we update the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.*

Comment: Some commenters did not support the proposal to change the assignment of F43.81 *Prolonged grief disorder* and F43.89 *Other reactions to severe stress* to Return to Provider instead of Medical Management. Their rationale was that a subset of SNFs that specialize in behavioral and mental health treatment may require use of these two new diagnosis codes as the primary diagnosis codes to meet beneficiary needs.

Response: We believe that even in such cases as the commenters described, there are many other behavioral and mental health diagnoses available that would serve as a more appropriate primary diagnosis for a SNF stay and, therefore, assigning these two codes to Return to Provider would not impede access to care for beneficiaries.

Comment: Several commenters suggested additional changes to the PDPM ICD–10 code mappings that were outside the scope of this rulemaking. Specifically, they requested that we consider changing M62.81 *Muscle weakness (generalized)* from Return to Provider to the Non-surgical orthopedic/musculoskeletal clinical category; adding several dysphasia codes to the SLP comorbidity mapping (namely, R13.14 *Dysphagia, pharyngoesophageal phase,* R13.11 *Dysphagia, oral phase,* R13.12 *Dysphagia, oropharyngeal phase,* R13.13 *Dysphagia, pharyngeal phase,* and R13.19 *Other dysphagia*); and adding a range of ICD–10 codes from J00 *Acute nasopharyngitis [common cold]* to J06.9 *Acute upper respiratory infection, unspecified* to the SLP comorbidity mapping.

Response: We note that the changes suggested by these commenters are outside the scope of this rulemaking, and will not be addressed in this rule. We will further consider the suggested changes to the ICD–10 code mappings and may implement them in the future as appropriate. To the extent that such changes are non-substantive, we may issue them in a future subregulatory update if appropriate; however, if such changes are substantive changes, in accordance with the update process established in the FY 2020 SNF PPS final rule, such changes must undergo full notice and comment rulemaking, and thus may be included in future rulemaking. See the discussion of the update process for the ICD–10 code mappings in the FY 2020 SNF PPS final rule (84 FR 38750) for more information.

After consideration of public comments, we are finalizing the changes as proposed.

3. Clinical Category Changes for Unspecified Substance Use Disorder Codes

Effective with stays beginning on and after October 1, 2022, ICD–10 diagnosis codes F10.90 *Alcohol use, unspecified, uncomplicated,* F10.91 *Alcohol use, unspecified, in remission,* F11.91 *Opioid use, unspecified, in remission,* F12.91 *Cannabis use, unspecified, in remission,* F13.91 *Sedative, hypnotic or anxiolytic use, unspecified, in remission,* and F14.91 *Cocaine use, unspecified, in remission* went into effect and were mapped to the clinical category of Medical Management. We reviewed these 6 new substance use disorder (SUD) codes and changed the assignment from Medical Management to Return to Provider because the codes are not specific as to if they refer to abuse or dependence, and there are other specific codes available for each of these conditions that would be more appropriate as a primary diagnosis for a SNF stay. For example, diagnosis code F10.90 *Alcohol use, unspecified, uncomplicated* is not specific as to whether the patient has alcohol abuse or alcohol dependence. There are more specific codes that could be used instead, such as F10.10 *Alcohol abuse, uncomplicated* or F10.20 *Alcohol dependence, uncomplicated,* that may serve as the primary diagnosis for a SNF stay and are appropriately mapped to the clinical category of Medical Management.

Moreover, we believe that increased accuracy of coding a patient's primary diagnosis aligns with CMS' broader efforts to ensure better quality of care. Therefore, we reviewed all 458 ICD–10 SUD codes from code categories F10 to F19 and finalized reassigning 162 additional unspecified SUD codes to Return to Provider from Medical Management because the codes are not specific as to if they refer to abuse or dependence. We would note that this policy change would not affect a large number of SNF stays. Our data from FY 2021 show that the 162 unspecified SUD codes were used as primary diagnoses for only 323 SNF stays (0.02 percent) and as secondary diagnoses for 9,537 SNF stays (0.54 percent). The purpose of enacting this policy is to continue an ongoing effort to refine the PDPM ICD–10 code mappings each year to ensure more accurate coding of primary diagnoses. We would encourage providers to continue reporting these codes as secondary diagnoses, to ensure that we are able to identify these patients and that they are receiving appropriate care.

Table 1, *Proposed Clinical Category Changes for Unspecified Substance Use Disorder Codes,* which lists all 168 codes included in this proposal, was posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.* We solicited comments on the proposed substantive changes to the PDPM ICD–10 code mappings discussed in this section, as well as comments on additional substantive and nonsubstantive changes that commenters believe are necessary.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the PDPM clinical category changes for unspecified SUD codes as proposed. However, several commenters did not agree with the use of F10.10 *Alcohol abuse, uncomplicated* or F10.20 *Alcohol dependence, uncomplicated,* as these examples do not align with the ICD–10–CM Official Guidelines for Coding and Reporting and the SNF provider would not be able to assign a code such as F10.10 or F10.20 without physician documentation to support that alcohol abuse or dependence was present.

Response: We appreciate the positive comments that we received supporting our efforts to map SUD diagnoses more accurately under the PDPM. We would note that the examples provided for alcohol abuse and dependence diagnosis were not intended to be diagnostic guidance, and the facility should assess the patient to identify the specific primary diagnosis that requires daily skilled care.

Comment: Some commenters opposed the PDPM clinical category changes for unspecified SUD codes due to concerns about administrative burden. While they acknowledged that there are more appropriate codes that can be used to indicate whether the patient has substance abuse or dependence, they believe that it is the responsibility of the referring physician to code at the highest level of specificity, and query rules make it complex for SNFs to recommend more specific codes to the physician.

Response: We appreciate that commenters agree there are more appropriate codes that can be used to indicate whether the patient has substance abuse or dependence. We continue to believe that appropriate treatment requires specificity in the coding of the diagnoses, which aligns with CMS' broader efforts to ensure better quality of care. Moreover, we believe that the plan of care for a patient should not only depend upon the diagnoses of the referring physician, but also on the assessment of the SNF care team, which includes the clinicians caring for the patient at the facility.

After consideration of public comments, we are finalizing the changes as proposed.

4. Clinical Category Changes for Certain Subcategory Fracture Codes

Each year, we solicit comments on additional substantive and nonsubstantive changes that commenters believe are necessary to the PDPM ICD–10 code mappings. In the FY 2023 final rule (87 FR 47524), we described how one commenter recommended that CMS consider revising the PDPM ICD–10 code mappings to reclassify certain subcategory S42.2—humeral fracture codes. The commenter highlighted that certain encounter codes for humeral fractures, such as those ending in the 7th character of A for an initial encounter for fracture, are permitted the option to be mapped to a surgical clinical category, denoted on the PDPM ICD–10 code mappings as May be Eligible for One of the Two Orthopedic Surgery Categories (that is, major joint replacement or spinal surgery, or orthopedic surgery) if the patient had a major procedure during the prior inpatient stay that impacts the SNF care plan. However, the commenter noted that other encounter codes within the same code family, such as those ending in the 7th character of D for subsequent encounter for fracture with routine healing, are mapped to the Non-Surgical Orthopedic/Musculoskeletal without the surgical option. The commenter requested that we review all subcategory S42.2—fracture codes to ensure that the appropriate surgical clinical category could be selected for joint aftercare. Since then, the commenter has also contacted CMS with a similar suggestion for M84.552D *Pathological fracture in neoplastic disease, left femur,* subsequent encounter for fracture with routine healing.

We have since reviewed the suggested code subcategories to determine the most efficient manner for addressing this discrepancy. We proposed adding the surgical option that allows 45 subcategory S42.2—codes for displaced fractures to be eligible for one of two orthopedic surgery categories. However, we noted that this does not extend to subcategory S42.2—codes for nondisplaced fractures, which typically do not require surgery. We also proposed adding the surgical option to subcategory 46 M84.5—codes for pathological fractures to certain major weight-bearing bones to be eligible for one of two orthopedic surgery categories.

Table 2, *Proposed Clinical Category Changes for S42.2 and M84.5 Fracture Codes,* which lists all 91 codes included in this proposal, was posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.* We solicited comments on the proposed substantive changes to the PDPM ICD–10 code mappings discussed in this section, as well as comments on additional substantive and nonsubstantive changes that commenters believe are necessary.

We did not receive public comments on this provision, and therefore, we are finalizing the changes as proposed.

5. Clinical Category Changes for Unacceptable Principal Diagnosis Codes

In the FY 2023 final rule (87 FR 47525), we described how several commenters referred to instances when SNF claims were denied for including a primary diagnosis code that was listed on the PDPM ICD–10 code mappings as a valid code, but was not accepted by some Medicare Administrative Contractors (MACs) that use the Hospital Inpatient Prospective Payment System (IPPS) Medicare Code Editor (MCE) lists when evaluating the primary diagnosis codes listed on SNF claims. In the IPPS, a patient's diagnosis is entered into the Medicare claims processing systems and subjected to a series of automated screens called the MCE. The MCE lists are designed to identify cases that require further review before classification into an MS–DRG. We noted that all codes on the MCE lists are able to be reported; however, a code edit may be triggered that the MAC may either choose to bypass or return to the provider to resubmit. Updates to the MCE lists are proposed on an annual basis and discussed through IPPS rulemaking when new codes or policies involving existing codes are introduced.

Commenters recommended that CMS seek to align the PDPM ICD–10 code mappings with the MCE in treating diagnoses that are Return to Provider, specifically referring to the *Unacceptable Principal Diagnosis* edit code list in the Definition of Medicare Code Edits, which was posted on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/ms-drg-classifications-and-software.* The *Unacceptable Principal Diagnosis* edit code list contains selected codes that describe a circumstance that influences an individual's health status but not a current illness or injury, or codes that are not specific manifestations but may be due to an underlying cause, and

which are considered unacceptable as a principal diagnosis.

We identified 95 codes from the MCE *Unacceptable Principal Diagnosis* edit code list that were mapped to a valid clinical category on the PDPM ICD–10 code mappings, and that were coded as primary diagnoses for 14,808 SNF stays (0.84 percent) in FY 2021. Table 3, *Proposed Clinical Category Changes for Unacceptable Principal Diagnosis Codes,* which lists all 95 codes included in this proposal, was posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.* As stated previously in this section of this final rule, we note that reporting these codes as a primary diagnosis for a SNF stay may trigger an edit that the MAC may either choose to bypass or return to the provider to resubmit, and therefore not all of these 14,808 stays were denied by the MACs.

After clinical review, we concurred that the 95 codes listed in Table 3 on the CMS website should be assigned to Return to Provider. For the diagnosis codes listed in Table 3 on the CMS website that are from the category B95 to B97 range and contain the suffix ''as the cause of diseases classified elsewhere'', the ICD–10 coding convention for such etiology and manifestation codes, where certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology, dictates that the underlying condition should be sequenced first, followed by the manifestation. The ICD–10 coding guidelines also state that codes from subcategory G92.0—*Immune effector cell-associated neurotoxicity syndrome,* subcategory R40.2—*Coma scale,* and subcategory S06.A—*Traumatic brain injury* should only be reported as secondary diagnoses, as there are more specific codes that should be sequenced first. Additionally, the ICD–10 coding guidelines state that diagnosis codes in categories Z90 and Z98 are status codes, indicating that a patient is either a carrier of a disease or has the sequelae or residual of a past disease or condition, and are not reasons for a patient to be admitted to a SNF. Lastly, our clinicians determined that diagnosis code Z43.9 *Encounter for attention to unspecified artificial opening* should be assigned to the clinical category Return to Provider because there are more specific codes that identify the site for the artificial opening.

Therefore, we proposed to reassign the 95 codes listed in Table 3 on the CMS website from the current default clinical category on the PDPM ICD–10 code mappings to Return to Provider. We also proposed to make future updates to align the PDPM ICD–10 code mappings with the MCE *Unacceptable Principal Diagnosis* edit code list on a subregulatory basis going forward. Moreover, we solicited comment on aligning with the MCE *Manifestation codes not allowed as principal diagnosis* edit code list, which contains diagnosis codes that are the manifestation of an underlying disease, not the disease itself, and therefore should not be used as a principal diagnosis, and the *Questionable admission codes* edit code list, which contains diagnoses codes that are not usually sufficient justification for admission to an acute care hospital. While these MCE lists were not mentioned by commenters, we believed that some MACs may be applying these edit lists to SNF claims and this could cause continued differences between the PDPM ICD–10 code mappings and the IPPS MCE. Finally, we proposed to make future updates to align the PDPM ICD–10 code mappings with the MCE *Manifestation codes not allowed as principal diagnosis* edit code list and the *Questionable admission codes* edit code list on a subregulatory basis going forward.

We solicited comments on the proposed substantive changes to the PDPM ICD–10 code mappings discussed in this section, as well as comments on additional substantive and nonsubstantive changes that commenters believe are necessary. We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

VII. Skilled Nursing Facility Quality Reporting Program (SNF QRP)

A. Background and Statutory Authority

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act, and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-critical access hospital (CAH) swing-bed rural hospitals. Section 1888(e)(6)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual market basket percentage increase described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year (FY), after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for that FY. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890(a) of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the SNF QRP. We have codified our program requirements in our regulations at 42 CFR part 413.

In the proposed rule, we proposed to adopt three new measures, remove three existing measures, and modify one existing measure. Second, we sought information on principles we could use to select and prioritize SNF QRP quality measures in future years. Third, we provided an update on our health equity efforts. Fourth, we proposed several administrative changes, including a change to the SNF QRP data completion thresholds and a new data submission method for the proposed CoreQ: Short Stay Discharge questionnaire. Finally, we proposed to begin the public reporting of four measures.

B. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we use for the selection of SNF QRP quality, resource use, or other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

1. Quality Measures Currently Adopted for the FY 2024 SNF QRP

The SNF QRP currently has 16 measures for the FY 2024 SNF QRP, which are listed in Table C1. For a discussion of the factors used to evaluate whether a measure should be removed from the SNF QRP, we refer readers to § 413.360(b)(2).

TABLE 11—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2024 SNF QRP

Short name	Measure name & data source
Resident Assessment Instrument Minimum Data Set (Assessment-Based)	
Pressure Ulcer/Injury.	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls.	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).
Application of Functional Assessment/ Care Plan.	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.

TABLE 11—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2024 SNF QRP—Continued

Short name	Measure name & data source
Change in Mobility Score.	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients.
Discharge Mobility Score.	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.
Change in Self-Care Score.	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients.
Discharge Self-Care Score.	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients.
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post-Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
TOH-Provider*	Transfer of Health (TOH) Information to the Provider Post-Acute Care (PAC).
TOH-Patient*	Transfer of Health (TOH) Information to the Patient Post-Acute Care (PAC).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
SNF HAI	SNF Healthcare-Associated Infections (HAI) Requiring Hospitalization.
NHSN	
HCP COVID–19 Vaccine.	COVID–19 Vaccination Coverage among Healthcare Personnel (HCP).

TABLE 11—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2024 SNF QRP—Continued

Short name	Measure name & data source
HCP Influenza Vaccine.	Influenza Vaccination Coverage among Healthcare Personnel (HCP).

*In response to the public health emergency (PHE) for the Coronavirus Disease 2019 (COVID–19), we released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for collection and reporting of the Transfer of Health (TOH) Information measures for at least 2 full fiscal years after the end of the PHE. The compliance date for the collection and reporting of the Transfer of Health Information measures was revised to October 1, 2023 in the FY 2023 SNF PPS final rule (87 FR 47547 through 47551).

C. SNF QRP Quality Measure Updates

In the proposed rule, we included SNF QRP proposals for the FY 2025 and FY 2026 program years. We proposed to add new measures to the SNF QRP as well as remove measures from the SNF QRP. Beginning with the FY 2025 SNF QRP, we proposed to (1) modify the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure, (2) adopt the Discharge Function Score measure,[12] which we specified under section 1888(e)(6)(B)(i) of the Act, and (3) remove three current measures: (i) the Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure, (ii) the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients measure, and (iii) the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients measure.

We also proposed two new measures beginning with the FY 2026 SNF QRP: (i) the CoreQ: Short Stay Discharge measure which we are specifying under section 1899B(d)(1) of the Act, and (ii) the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, which we are specifying under section 1899B(d)(1) of the Act.

[12] This measure was submitted to the Measures Under Consideration (MUC) List as the Cross-Setting Discharge Function Score. Subsequent to the MAP Workgroup meetings, the measure developer modified the name. Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

1. SNF QRP Quality Measure Updates Beginning With the FY 2025 SNF QRP

a. Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2025 SNF QRP

(1) Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[13] Subsequently, in the FY 2022 SNF PPS final rule (86 FR 42480 through 42489), we adopted the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) (HCP COVID–19 Vaccine) measure for the SNF QRP. The HCP COVID–19 Vaccine measure requires each SNF to submit data on the percentage of HCP eligible to work in the SNF for at least one day during the reporting period, excluding persons with contraindications to FDA-authorized or -approved COVID–19 vaccines, who have received a complete vaccination course against SARS–CoV–2. Since that time, COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.13 million deaths in the United States as of June 19, 2023.[14] In recognition of the ongoing significance and complexity of COVID–19, the Secretary has renewed the PHE on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 9, 2023.[15] The Department of Health and Human Services (HHS) let the PHE expire on May 11, 2023. However, HHS stated that the public health response to COVID–19 remains a public health priority with a whole of government approach to combating the virus, including through vaccination efforts.[16]

[13] U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response. Determination that a Public Health Emergency Exists. January 31, 2020. *https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx.*

[14] Centers for Disease Control and Prevention. COVID Data Tracker. June 19, 2023. *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[15] U.S. Department of Health and Human Services, Administration for Strategic for Preparedness and Response. Renewal of Determination that a Public Health Emergency Exists. February 9, 2023. *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.*

[16] U.S. Department of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. *https://www.hhs.gov/about/news/2023/02/09/fact-*

Continued

In the FY 2022 SNF PPS final rule (86 FR 42480 through 42489) and in the Revised Guidance for Staff Vaccination Requirements,[17] we stated that vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination in SNFs through quality measurement in order to protect HCP, residents, and caregivers, and to help sustain the ability of SNFs to continue serving their communities after the PHE. At the time we issued the FY 2022 SNF PPS final rule (86 FR 42480 through 42489) where we adopted the HCP COVID–19 Vaccine measure, the Food and Drug Administration (FDA) had issued emergency use authorizations (EUAs) for COVID–19 vaccines manufactured by Pfizer-BioNTech,[18] Moderna,[19] and Janssen.[20] The Pfizer-BioNTech vaccine was authorized for ages 12 and older and the Moderna and Janssen vaccines for ages 18 and older. Shortly following the publication of the FY 2022 SNF PPS final rule, on August 23, 2021, the FDA issued an approval for the Pfizer-BioNTech vaccine, marketed as Comirnaty.[21] The FDA issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022 [22] and an EUA for the Novavax vaccine, on July 13, 2022.[23] The FDA also issued EUAs for single booster doses of the then authorized COVID–19 vaccines. As of November 19, 2021 [24 25 26] a single booster dose of each COVID–19 vaccine was authorized for all eligible individuals 18 years of age and older. EUAs were subsequently issued for a second booster dose of the Pfizer-BioNTech and Moderna vaccines in certain populations in March 2022.[27] FDA first authorized the use of a booster dose of bivalent or ''updated'' COVID–19 vaccines from Pfizer-BioNTech and Moderna in August 2022.[28]

(a) Measure Importance

While the impact of COVID–19 vaccines on asymptomatic infection and transmission is not yet fully known, there are now robust data available on COVID–19 vaccine effectiveness across multiple populations against severe illness, hospitalization, and death. Two-dose COVID–19 vaccines from Pfizer-BioNTech and Moderna were found to be 88 percent and 93 percent effective against hospitalization for COVID–19, respectively, over 6 months for adults over age 18 without immunocompromising conditions.[29] During a SARS–CoV–2 surge in the spring and summer of 2021, 92 percent of COVID–19 hospitalizations and 91 percent of COVID–19-associated deaths were reported among persons not fully vaccinated.[30] Real-world studies of population-level vaccine effectiveness indicated similarly high rates of efficacy in preventing SARS–CoV–2 infection among frontline workers in multiple industries, with a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[31] Vaccines have also been highly effective in real-world conditions at preventing COVID–19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[32] In the presence of high community prevalence of COVID–19, residents of nursing homes with low staff vaccination coverage had cases of COVID–19 related deaths 195 percent higher than those among residents of nursing homes with high staff vaccination coverage.[33] Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, hospitalization, and death.

As SARS–CoV–2 persists and evolves, our COVID–19 vaccination strategy must remain responsive. When we adopted the HCP COVID–19 Vaccine measure in the FY 2022 SNF PPS final rule, we stated that the need for booster doses of COVID–19 vaccine had not been established and no additional doses had been recommended (86 FR 42484 through 42485). We also stated

sheet-covid-19-public-health-emergency-transition-roadmap.html.

[17] Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO–23–02–ALL. October 26, 2022. *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[18] Food and Drug Administration. FDA Takes Key Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for First COVID–19 Vaccine. December 11, 2020. *https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.*

[19] Food and Drug Administration. FDA Takes Additional Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for Second COVID–19 Vaccine. December 18, 2020. *https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.*

[20] Food and Drug Administration. FDA Issues Emergency Use Authorization for Third COVID–19 Vaccine. February 27, 2021. *https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.*

[21] Food and Drug Administration. FDA Approves First COVID–19 Vaccine. August 23, 2021. *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.*

[22] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Takes Key Action by Approving Second COVID–19 Vaccine. January 31, 2022. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.*

[23] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Authorizes Emergency Use of Novavax COVID–19 Vaccine, Adjuvanted. July 13, 2022. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted.*

[24] Food and Drug Administration. FDA Authorizes Booster Dose of Pfizer-BioNTech COVID–19 Vaccine for Certain Populations. September 22, 2021. *https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations.*

[25] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID–19 Vaccines. October 20, 2021. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines.*

[26] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Expands Eligibility for COVID–19 Vaccine Boosters. November 19, 2021. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters.*

[27] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Authorizes Second Booster Dose of Two COVID–19 Vaccines for Older and Immunocompromised Individuals. March 29, 2022. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and.*

[28] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. August 31, 2022. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.*

[29] Self WH, Tenforde MW, Rhoads JP, et al. Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID–19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March-August 2021. MMWR Morb Mortal Wkly Rep 2021;70:1337–1343. doi: 10.15585/mmwr.mm7038e1. *https://www.cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm.*

[30] Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID–19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1284–1290. doi: 10.15585/mmwr.mm7037e1. *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm.*

[31] Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID–19 Vaccines in Preventing SARS–CoV–2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021. MMWR Morb Mortal Wkly Rep 2021 Aug 27;70(34):1167–1169. doi: 10.15585/mmwr.mm7034e4. *https://cdc.gov/mmwr/volume/70/wr/mm7034e4.htm?s_cid=mm7034e4_w.*

[32] Pilishvili T, Gierke R, Fleming-Dutra KE, et al. Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. N Engl J Med. 2021 Dec 16;385(25):e90. doi: 10.1056/NEJMoa2106599. PMID: 34551224; PMCID: PMC8482809.

[33] McGarry BE, Barnett ML, Grabowski DC, Gandhi AD. Nursing Home Staff Vaccination and Covid–19 Outcomes. N Engl J Med. 2022 Jan 27;386(4):397–398. doi: 10.1056/NEJMc2115674. PMID: 34879189; PMCID: PMC8693685.

that we believed the numerator was sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and that the measure was sufficiently specified to address boosters (86 FR 42485). Since we adopted the HCP COVID–19 Vaccine measure in the FY 2022 SNF PPS final rule, new variants of SARS–CoV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the Centers for Disease Control and Prevention (CDC) because it spreads more easily than earlier variants.[34] Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID–19 vaccines, which include a component of the original virus strain, to provide broad protection against COVID–19 and a component of the Omicron variant, to provide better protection against COVID–19 caused by the Omicron variant.[35] These booster doses of the bivalent COVID–19 vaccines have been shown to increase immune response to SARS–CoV–2 variants, including Omicron, particularly in individuals that are more than 6 months removed from receipt of their primary series.[36] The FDA issued EUAs for booster doses of two bivalent COVID–19 vaccines, one from Pfizer-BioNTech [37] and one from Moderna,[38] and strongly encourages anyone who is eligible to consider receiving a booster dose with a bivalent COVID–19 vaccine to provide better protection against currently circulating variants.[39] COVID–19 booster doses are associated with a greater reduction in infections among HCP relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only a two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[40] [41]

We believe that vaccination remains the most effective means to prevent the severe consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, the continued presence of SARS–CoV–2 in the United States, and variance among rates of booster dose vaccination, it is important to update the specifications of the HCP COVID–19 Vaccine measure to refer to HCP who receive primary series and booster doses in a timely manner. Given the persistent spread of COVID–19, we continue to believe that monitoring and surveillance of vaccination rates among HCP are important and provides residents, beneficiaries, and their caregivers with information to support informed decision making. Beginning with the FY 2025 SNF QRP, we proposed to modify the HCP COVID–19 Vaccine measure to replace the term ''complete vaccination course'' with the term ''up to date'' in the HCP vaccination definition. We also proposed to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the FY 2025 SNF QRP.

(b) Measure Testing

The CDC conducted beta testing of the modified HCP COVID–19 Vaccine measure by assessing if the collection of information on booster doses received by HCP was feasible, as information on receipt of booster doses is required for determining if HCP are up to date with the current COVID–19 vaccination. Feasibility was assessed by calculating the proportion of facilities that reported booster doses of the COVID–19 vaccine. The assessment was conducted in various facility types, including SNFs, using vaccine coverage data for the first quarter of calendar year (CY) 2022 (January to March), which was reported through the CDC's National Healthcare Safety Network (NHSN). Feasibility of reporting booster doses is evident by the fact that 99.2 percent of SNFs reported vaccination booster dose coverage data to the NHSN for the first quarter of 2022.[42] Additionally, HCP COVID–19 Vaccine measure scores calculated using January 1 to March 31, 2022 data had a median of 31.8 percent and an interquartile range of 18.9 to 49.7 percent, indicating a measure performance gap as there are clinically significant differences in booster dose vaccination coverage rates among SNFs.[43]

(2) Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act be endorsed by a consensus-based entity (CBE) with a contract under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The current version of the HCP COVID–19 Vaccine measure recently received endorsement by the CBE on July 26, 2022 under the name ''Quarterly Reporting of COVID–19 Vaccination Coverage Among Healthcare Personnel.'' [44] However, this measure received endorsement based on its specifications depicted in the FY 2022 SNF PPS final rule (86 FR 42480 through 42489), and does not capture information about whether HCP are up to date with their COVID–19 vaccinations. The proposed

[34] Centers for Disease Control and Prevention. Variants of the Virus. *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html.*

[35] Food and Drug Administration. COVID–19 Bivalent Vaccine. *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines.*

[36] Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine Against COVID–19. N Engl J Med. 2022 Oct 6;387(14):1279–1291. doi: 10.1056/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

[37] Food and Drug Administration. Pfizer-BioNTech COVID–19 Vaccines. *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines.*

[38] Food and Drug Administration. Moderna COVID–19 Vaccines. *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines.*

[39] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. August 31, 2022. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.*

[40] Prasad N, Derado G, Nanduri SA, et al. Effectiveness of a COVID–19 Additional Primary or Booster Vaccine Dose in Preventing SARS–CoV–2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant—United States, February 14–March 27, 2022. MMWR Morb Mortal Wkly Rep. 2022 May 6;71(18):633–637. doi: 10.15585/mmwr.mm7118a4. PMID: 35511708; PMCID: PMC9098239.

[41] Oster Y, Benenson S, Nir-Paz R, Buda I, Cohen MJ. The Effect of a Third BNT162b2 Vaccine on Breakthrough Infections in Health Care Workers: a Cohort Analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1–735.e3. doi: 10.1016/j.cmi.2022.01.019. PMID: 35143997; PMCID: PMC8820100.

[42] National Quality Forum. Measure Application Partnership (MAP) Post-Acute Care/Long-Term Care: 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications. December 1, 2022. *https://mmshub.cms.gov/sites/default/files/map-pac-muc-measure-specifications-2022-2023.pdf.*

[43] National Quality Forum. Measure Application Partnership (MAP) Post-Acute Care/Long-Term Care: 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications. December 1, 2022. *https://mmshub.cms.gov/sites/default/files/map-pac-muc-measure-specifications-2022-2023.pdf.*

[44] Partnership for Quality Measurement. Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel. Accessed June 28, 2023. *https://p4qm.org/measures/3636.*

modification of this measure utilizes the term up to date in the HCP vaccination definition and updates the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines. We are unable to identify any measures endorsed or adopted by a consensus organization for SNFs that captured information on whether HCP are up to date with their COVID–19 vaccinations, and we found no other feasible and practical measure on this topic.

Therefore, after consideration of other available measures, we found that the exception under section 1899B(e)(2)(B) of the Act applies and proposed the modified measure, HCP COVID–19 Vaccine, beginning with the FY 2025 SNF QRP. The CDC, the measure developer, is pursuing CBE endorsement for the modified version of the measure.

(3) Measure Applications Partnership (MAP) Review

We refer readers to the FY 2022 SNF PPS final rule (86 FR 42482) for more information on the initial review of the HCP COVID–19 Vaccine measure by the Measure Applications Partnership (MAP).

In accordance with section 1890A of the Act, the pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List, that the Secretary is considering adopting for use in the Medicare program(s), including our quality reporting programs. This allows interested parties to provide recommendations to the Secretary on the measures included on the MUC List. We submitted the updated version of the HCP COVID–19 Vaccine measure on the MUC List entitled ''List of Measures under Consideration for December 1, 2022'' [45] for the 2022 to 2023 pre-rulemaking cycle for consideration by the MAP. Interested parties submitted four comments to the MAP during the pre-rulemaking process on the proposed modifications of the HCP COVID–19 Vaccine measure. Three commenters noted that it is important that HCP be vaccinated against COVID–19 and supported measurement and reporting as an important strategy to help healthcare organizations assess their performance in achieving high rates of up to date vaccination of their HCP. One of these commenters noted that the measure would provide valuable information to the government as part of its ongoing response to the pandemic. The other two commenters do not believe it should be used in a pay-for-performance program, and one raised concerns of potential unintended consequences, such as frequency of reporting and the potential State regulations with which such a requirement might conflict. One commenter did not support the measure, raising several concerns with the measure, including that the data have never been tested for validity or reliability. Finally, three of the four commenters raised concern about the difficulty of defining up to date for purposes of the modified measure.

Shortly after publication of the MUC List, several MAP workgroups met to provide input on the measure. First, the MAP Health Equity Advisory Group convened on December 6 to 7, 2022. The MAP Health Equity Advisory Group questioned whether the measure excludes residents with contraindications to FDA authorized or approved COVID–19 vaccines, and whether the measure will be stratified by demographic factors. The measure developer (that is, the CDC) confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but the measure will not be stratified since the data are submitted at an aggregate rather than an individual level.

The MAP Rural Health Advisory Group met on December 8 to 9, 2022, during which a few members expressed concerns about data collection burden, given that small rural hospitals may not have employee health software. The measure developer acknowledged the challenge of getting adequate documentation and emphasized their goal is to ensure the measures do not present a burden on the provider. The measure developer also noted that the model used for the HCP COVID–19 Vaccine measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified HCP COVID–19 Vaccine measure if vaccination strategy becomes seasonal. The measure developer acknowledged that if COVID–19 becomes seasonal, the measure model could evolve to capture seasonal vaccination.

Next, the MAP Post-Acute Care/Long-Term Care (PAC/LTC) workgroup met on December 12, 2022 and provided input on the proposed modification for the HCP COVID–19 Vaccine measure. The MAP PAC/LTC workgroup noted that the previous version of the measure received endorsement from the CBE (CBE #3636),[46] and that the CDC intends to submit the updated measure for endorsement. The PAC/LTC workgroup voted to support the staff recommendation of conditional support for rulemaking pending testing indicating the measure is reliable and valid, and endorsement by the CBE.

Following the PAC/LTC workgroup meeting, a public comment period was held in which interested parties commented on the PAC/LTC workgroup's preliminary recommendations, and the MAP received three comments. Two supported the update to the measure, one of which strongly supported the vaccination of HCP against COVID–19. Although these commenters supported the measure, one commenter recommended CBE endorsement for the updated measure, and encouraged us to monitor any unintended consequences from the measure. Two commenters noted the challenges associated with the measure's specifications. Specifically, one noted the broad definition of the denominator and another recommended a vaccination exclusion or exception due to religious beliefs. Finally, one commenter raised issues related to the time lag between data collection and public reporting on Care Compare and encouraged us to provide information as to whether the measure is reflecting vaccination rates accurately and encouraging HCP vaccination.

The MAP Coordinating Committee convened on January 24 to 25, 2023, during which the measure was placed on the consent calendar and received a final recommendation of conditional support for rulemaking pending testing indicating the measure is reliable and valid, and endorsement by the CBE. We refer readers to the final MAP recommendations, titled *2022–2023 MAP Final Recommendations.*[47]

(4) Quality Measure Calculation

The HCP COVID–19 Vaccine measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as SNFs. The HCP COVID–19 Vaccine measure is a process measure and is not risk-adjusted.

The denominator would be the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons

[45] Centers for Medicare & Medicaid Services. Overview of the List of Measures Under Consideration for December 1, 2022. *https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf.*

[46] Partnership for Quality Measurement. Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel. Accessed June 28, 2023. *https://p4qm.org/measures/3636.*

[47] 2022–2023 MAP Final Recommendations. *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

with contraindications to COVID–19 vaccination that are described by the CDC.[48] SNFs report the following four categories of HCP to NHSN, and the first three categories are included in the measure denominator:

- *Employees:* This includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.
- *Licensed independent practitioners (LIPs):* This includes physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility, but are not directly employed by it (that is, they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.
- *Adult students/trainees and volunteers:* This includes all medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or over who are affiliated with the healthcare facility, but are not directly employed by it (that is, they do not receive a direct paycheck from the facility), regardless of clinical responsibility or patient contact.
- *Other contract personnel:* Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the above-mentioned denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data from this category are not included in the HCP COVID–19 Vaccine measure.[49]

The denominator excludes denominator-eligible individuals with contraindications as defined by the CDC.[50] We did not propose any changes to the denominator exclusions.

We proposed the numerator would be the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID–19 vaccines. Providers would refer to the definition of up to date as of the first day of the applicable reporting quarter, which can be found at *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf.* For example, HCP would have been considered up to date during quarter 4 of the CY 2022 reporting period for the SNF QRP if they met one of the following criteria:

1. Individuals who received an updated bivalent[51] booster dose, or

2a. Individuals who received their last booster dose less than 2 months ago, or

2b. Individuals who completed their primary series[52] less than 2 months ago.

We refer readers to *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-rev-2023-508.pdf* for more details on the measure specifications.[53]

While we did not propose any changes to the data submission or reporting process for the HCP COVID–19 Vaccine measure, we proposed that for purposes of meeting FY 2025 SNF QRP compliance, SNFs would report HCP who are up to date beginning in quarter 4 of CY 2023. Under the data submission and reporting process, SNFs would collect the numerator and denominator for the modified HCP COVID–19 Vaccine measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Long-Term Care Facility (LTCF) Component before the quarterly deadline. In the FY 2024 SNF PPS proposed rule (88 FR 21337), we incorrectly stated that SNFs would submit data to the NHSN Healthcare Personnel Safety (HPS) Component. We clarify that SNFs submit the data for this measure to the NHSN LTCF Component. We highlight that SNFs already submit data to the LTCF component of the NHSN for reporting of the HCP COVID–19 Vaccine measure. If a SNF submits more than 1 week of data in a month, the most recent week's data would be used to calculate the measure. Each quarter, the CDC would calculate a single quarterly HCP COVID–19 vaccination coverage rate for each SNF, which would be calculated by taking the average of the data from the 3 weekly rates submitted by the SNF for that quarter. Beginning with the FY 2026 SNF QRP, we proposed SNFs would be required to submit data for the entire calendar year. We also proposed that public reporting of the modified version of the HCP COVID–19 Vaccine measure would begin with the October 2024 Care Compare refresh or as soon as technically feasible.

We solicited public comment on our proposal to modify the HCP COVID–19 Vaccine measure beginning with the FY 2025 SNF QRP. We received several comments from interested parties who support vaccination of HCP and communities against COVID–19. They also agreed with our rationale underlying the proposal to adopt the modified measure in the SNF QRP because updating the measure numerator definition reflected the current science. However, many of these same commenters did not support the proposal itself for various reasons, including the lack of CBE endorsement, the perceived burden associated with collecting the data, and the definition of up to date. The following is a summary of the comments we received on our proposal to modify the HCP COVID–19 Vaccine measure beginning with the FY 2025 SNF QRP and our responses.

Comment: We received several supportive comments for our proposal to modify the numerator definition for the HCP COVID–19 Vaccine measure and to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines. Commenters note that nursing home residents have been disproportionately vulnerable throughout the COVID–19 pandemic, and although the PHE has ended, adherence to infection prevention and control measures is essential to the health, safety, and well-being of residents. Some commenters noted that access to transparent, complete, and easily understandable information is essential for residents to make informed decisions, and that public display of the vaccination rates on Care Compare provides vital information for residents and their caregivers. Other commenters also noted that despite CMS's withdrawal of the Omnibus COVID–19 Health Care Staff Vaccination Requirements,[54]

[48] Centers for Disease Control and Prevention. Contraindications and precautions. *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.*

[49] For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID–19 Vaccination Protocol, Weekly COVID–19 Vaccination Module for Healthcare Personnel, *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf.*

[50] Centers for Disease Control and Prevention. Contraindications and precautions. *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.*

[51] The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on September 2, 2022. As of this date, the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

[52] Completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine.

[53] We highlight that the hyperlink included in the FY 2024 SNF PPS proposed rule has been retired as the CDC has uploaded a new measure specification document to the NHSN. Therefore, the hyperlink has been updated in this FY 2024 SNF PPS final rule.

[54] We interpret the commenter to be referring to the Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the

Continued

vaccinations are still one of the most effective infection prevention tools to protect staff, residents, and visitors against severe illness, hospitalization, and death.

Response: We thank the commenters for their support. We agree that vaccination plays a critical part in the nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including SNFs, in order to protect HCP, residents, and caregivers, and to help sustain the ability of HCP in SNFs to continue serving their communities.

Comment: Three commenters opposed the proposed modification and expressed concern that the modified version of the measure was not submitted for endorsement by a CBE before it was proposed for the SNF QRP. As a result, one of these commenters is concerned that the measure has not received a full evaluation of a range of issues affecting measure reliability, accuracy, and feasibility. This commenter also stated that the current version of the measure never went through a CBE endorsement process, and therefore, it has not yet had a holistic evaluation regarding whether the measure is working as intended.

Response: We refer the commenter to section VII.C.1.a.2. of this final rule, where we point out that the current version of the HCP COVID–19 Vaccine measure received endorsement by the CBE on July 26, 2022 under the name ''Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel.'' [55] We note, however, that the measure received endorsement based on its specifications in the FY 2022 SNF PPS final rule (86 FR 42480 through 42489). Even though the current, endorsed version does not capture information about whether HCP are up to date with their COVID–19 vaccinations, we believe its previous endorsement speaks to the quality of the measure design for the proposed modified version, since many components of the previous measure remain intact in this modified version. Since we were unable to identify any CBE endorsed measures for SNFs that captured information on whether HCP are up to date with their COVID–19 vaccinations, and we found no other feasible and practical measure on this topic, we find the modification to the HCP COVID–19 Vaccine measure reasonable for SNF QRP adoption and implementation. The CDC, the measure developer, is pursuing CBE endorsement for the modified version of the HCP COVID–19 Vaccine measure.

In terms of measure testing, as mentioned in section VII.C.1.a.1.b. of this final rule, we reiterate that the CDC conducted beta testing of the modified HCP COVID–19 Vaccine measure and concluded that the collection of information on booster doses received by HCP was feasible with a high reporting rate and the measure score displayed a performance gap indicating clinically significant differences in booster dose vaccination coverage rates among SNFs. We will continue to monitor the measure to identify any concerning trends as part of our routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the SNF QRP.

Comment: A number of commenters expressed concerns with the evolving nature of the measure's definition of up to date. Commenters suggested that the definition will quickly and frequently become outdated, and that a measure with a ''moving set of goalposts'' is challenging for HCP to understand. As a result, these changes to the definition could result in an inaccurate reporting of HCPs' up to date vaccination rates. Another commenter was concerned that any inconsistencies in the up to date definitions and potential inaccuracies associated with the rapid translation of complex vaccination recommendations may cause confusion among SNFs and negatively impact vaccine uptake. Finally, one commenter suggested that without a regular cadence of boosters or a defined COVID–19 ''season,'' like influenza, modifying the numerator definition to up to date is premature.

Response: We recognize that the up to date COVID–19 vaccination definition may evolve due to the changing nature of the virus, but we are also confident in HCPs' ability to understand these changes as they have been at the front lines of managing COVID–19 since the beginning of the pandemic. Since the adoption of the current version of the measure, the public health response to COVID–19 has necessarily adapted to respond to the changing nature of the virus's transmission and community spread. As mentioned in the FY 2022 SNF PPS final rule (86 FR 42481 through 42482), we received several public comments during the measure's pre-rulemaking process encouraging us to continue to update the measure as new evidence on COVID–19 continues to arise and we stated our intention to continue to work with our partners, including the FDA and CDC, to consider any updates to the measure in future rulemaking as appropriate. We believe that the proposed modification to this measure aligns with our responsive approach to COVID–19 and will continue to support vaccination as the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death.

Comment: One commenter who supported the proposal to modify the HCP COVID–19 Vaccine numerator definition also recommended that the measure should explicitly specify for HCP to receive primary series and booster vaccine doses to align with the recommendations on bivalent booster doses, including being up to date.

Response: We agree with the commenter, and highlight that the proposed modification to the HCP COVID–19 Vaccine measure numerator is in alignment with CDC recommendations as found on the following CDC NHSN web page: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf.* At the beginning of each reporting period and before collecting or submitting data on this modified measure, SNFs must refer to the aforementioned document to determine the then-applicable definition of up to date to apply when collecting data on the vaccination status of HCP for that quarterly reporting period.

Comment: One commenter noted that CDC's vaccination guidance suggests that some individuals with certain risk factors should consider receiving a booster dose within 4 months of receiving their first bivalent dose. The commenter noted that SNFs usually do not have routine access to data to know which of their HCPs may need a booster dose. The commenter was concerned that, to collect accurate data, SNFs would have to obtain permission to inquire and obtain information on each individual HCP's underlying health risk factors and a mechanism to keep the data fully secure. As a result, they expressed concern that the resource intensiveness of collecting data under the CDC's proposed modified definition for the HCP COVID–19 Vaccine measure may outweigh its value.

Response: SNFs have been engaging with their staff for almost 2 years to obtain information on their COVID–19 vaccination status. The proposed modification to the HCP COVID–19

Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs–IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long-Term Care Facility COVID–19 Testing Requirements Final Rule (88 FR 36485).

[55] Partnership for Quality Measurement. Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel. Accessed on June 14, 2023. *https://p4qm.org/measures/3636.*

Vaccine measure should not require any changes to how SNFs currently engage with their staff and administer a comprehensive vaccine administration strategy. We are also confident in SNF's ability to utilize the available CDC resources to keep themselves informed as they have been at the front lines of managing COVID–19 since the beginning of the pandemic. Specifically, we note that considerations for immunocompromised persons are not impacted by the modification proposed to this measure as these considerations are present with the primary vaccination series for the current HCP COVID–19 Vaccine measure. As emphasized in the CDC NHSN ''COVID–19 Vaccination Modules: Understanding Key Terms and Up to Date Vaccination'' web page *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf* referred to in section VII.C.1.a.4. of this final rule, the NHSN surveillance definition for up to date is currently the same for all HCP regardless of immunocompromised status.

Comment: Two commenters expressed concern that modifications to the HCP COVID–19 Vaccine measure may exacerbate workforce shortages. One commenter noted that while the measure does not mandate up to date COVID–19 vaccinations for HCP, it may affect how SNFs approach vaccination requirements. One of these commenters mentioned that HCP may choose to work in other health care settings where such a mandate or quality measure does not exist, and the other commenter suggested they will choose to work in other areas of commerce.

Response: We disagree that the proposed modification to the numerator definition of the HCP COVID–19 Vaccine measure may exacerbate workforce shortages. We believe that the risks associated with COVID–19 warrant direct attention, especially because HCP are working directly with, and in close proximity to, residents. We clarify that the HCP COVID–19 Vaccine measure does not require SNFs to adopt mandatory vaccination policies, and it is a SNF's responsibility to determine their own personnel policies. To support a comprehensive vaccine administration strategy, we encourage SNFs to voluntarily engage in the provision of appropriate and accessible education and vaccine-offering activities. Many SNFs across the country are educating staff, residents, and residents' representatives, participating in vaccine distribution programs, and reporting up to date vaccine administration. The CDC has a number of resources available to SNFs to assist in building vaccine confidence. CMS also has a web page to help providers, including SNFs, find resources related to the COVID–19 vaccines. There are several toolkits and videos SNFs can use to stay informed and to educate their HCP, residents and communities about the COVID–19 vaccines.

Comment: Several commenters expressed concern with the measure's administrative burden, especially with having to track whether HCP meet the new requirements when the up to date definition changes. Another commenter suggested that because SNFs do not currently report booster doses to the NHSN, the proposal will require facility staff to spend more time tracking this information which will redirect resources away from direct resident care, particularly for smaller facilities without sophisticated software. Finally, one commenter expressed conditional support for the modification to the HCP COVID–19 measure but requested CMS reduce the reporting burden associated with the measure. This commenter requested that CMS and the CDC work with SNFs to identify opportunities to simplify and streamline any reporting burdens associated with the measure.

Response: We appreciate commenters' concerns regarding the reporting of the measure. SNFs have been reporting the current version of the measure since the measure's initial data submission period (October 1, 2021 through December 31, 2021), and we believe that there has been sufficient time to allocate the necessary resources required to report this measure. We note that the CDC used the up to date numerator definition during the Quarter 4 2022 surveillance period (September 26, 2022 through December 25, 2022) for purposes of NHSN surveillance, and SNFs have been successfully reporting the measure in alignment with the proposed modifications since that time. To assess the burden of reporting booster doses, the CDC conducted feasibility analysis of the modified HCP COVID–19 Vaccine measure by calculating the proportion of facilities that reported booster doses of the COVID–19 vaccine. As mentioned in section VII.C.1.a.1.b. of this final rule, feasibility of reporting booster doses of vaccine is evident by the fact that 99.2 percent of SNFs reported vaccination booster dose coverage data to the NHSN for the first quarter of 2022. Based on the high reportability, we do not believe the proposed change would impose overwhelming burden.

The CDC provides frequent communications and education to support SNFs' understanding of the latest guidelines. CDC posts an updated document approximately 2 weeks before the start of a new reporting quarter. If there are any changes to the definition, forms, etc., CDC will host a webinar in the 1–2 weeks before the beginning of a new reporting quarter. If SNFs have any concerns they would like to address regarding the data submission of this measure, they can voice their concerns during CMS' SNF/LTC Open Door Forums (ODFs). For more information on ODFs and to sign up for email notifications, we refer readers to the following CMS web page: *https://www.cms.gov/outreach-and-education/outreach/opendoorforums/odf_snfltc.*

Comment: One commenter emphasized that the reporting burden stems from the high frequency reporting cadence as well as the number of individuals included in the measure denominator. The same commenter stated that up to date COVID–19 vaccination data would not be easy to track, requires multiple processes, and frequent multiple software applications.

Response: We emphasize that we proposed no changes to the measure's reporting frequency, reporting method, or denominator population. SNFs have been successfully reporting at this cadence on the same HCP population since October 1, 2021.

Comment: Two commenters recommended the HCP COVID–19 Vaccine measure should be voluntary until there is a stable definition for up to date.

Response: The HCP COVID–19 Vaccine measure was adopted into the SNF QRP in the FY 2022 SNF PPS Final Rule (86 FR 42480 through 42489). We proposed to modify the definition of the measure numerator and the time frames for reporting and did not make any proposed changes to the measure denominator or the minimum reporting threshold for compliance. Therefore, successful reporting of the measure is still part of the SNF QRP reporting requirements.

Comment: One commenter raised concerns with the potential inaccuracy of the measure because the term up to date may continue to evolve with new vaccines and vaccine formulations.

Response: In response to the commenter's concerns that the up to date numerator definition may evolve, we refer commenters to section VII.C.1.a.4. of this final rule where we discuss how SNFs would refer to the definition of up to date as of the first day of the quarter, which can be found at the following CDC NHSN web page at *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf.* The CDC notes that this document will be updated quarterly to reflect any changes as COVID–19 guidance evolves,

and notes that SNFs would use the definitions for the reporting period associated with the reporting weeks included in data submission. As such, the up to date vaccination definition that would be applicable during a particular reporting period would not change, which addresses any concern that there would not be a single consistent resource for reporting instructions when the definition of up to date is revised. If the requirements do change from one quarter to the next, SNFs would have the up to date definition at the beginning of the quarter (using the aforementioned CDC NHSN web page), and have a minimum of three weeks to assess whether their HCP meet the definition of up to date before submitting HCP COVID–19 Vaccine measure data during the self-selected week of a corresponding month.

Comment: A number of commenters stated that while they support COVID–19 vaccination as one of the strongest measures for preventing serious illness and/or death from COVID–19, they do not believe the HCP COVID–19 Vaccine measure is an indicator of whether a SNF provides high quality of care to residents. Commenters noted that the measure, as currently written, reflects personal choice and represents outcomes over which SNFs have no control. Another commenter stated that staff acceptance of the COVID–19 vaccine reflects the community in which they reside, their own culture and beliefs, as well as their own health status. This commenter urged CMS to withdraw the HCP COVID–19 Vaccine measure from the SNF QRP and instead create a process measure to collect data on the outreach and education efforts that SNFs have undertaken to encourage up to date vaccination among staff. One commenter noted that differences in vaccine uptake are often deeply rooted in culture, religion, ethnicity, socioeconomic status, and more. Therefore, they believe that while SNFs will continue to educate their staff and encourage employee vaccinations, they should not be used to measure a SNF's ability to provide a safe environment. Finally, one commenter requested that CMS remind the public that vaccination is not mandatory for HCP, and as a result, the reported vaccination rate performance may vary based on local vaccine hesitancy barriers rather than provider effort at encouraging all HCP to be vaccinated.

Response: We disagree with the commenters and believe that the HCP COVID–19 Vaccine measure is an indicator of the quality of care in a SNF. We direct readers to section VII.C.1.a.1.a. of this final rule where we provide information illustrating that in the presence of a high community prevalence of COVID–19, residents of facilities with low staff vaccination coverage had cases of COVID–19-related deaths 195 percent higher than those among residents of facilities with high vaccination coverage.[56] Therefore, we find that a SNF's HCP COVID–19 vaccination rate, including booster doses, is an important quality indicator. We acknowledge that vaccination rates may be influenced by staff's culture, beliefs, community, and geographic areas, but we also know that HCP may come into contact with SNF residents, increasing the risk for HCP-to-resident transmission of infection. Therefore, we believe the measure as proposed has the potential to generate actionable data on up to date HCP COVID–19 vaccination rates that can be used to target quality improvement among SNFs, including increasing up to date HCP COVID–19 vaccination coverage in SNFs, while also promoting resident safety and increasing the transparency of quality of care in the SNF setting. Furthermore, we appreciate the suggestion for a quality measure to collect data on the outreach and education efforts that SNFs have undertaken to encourage up to date vaccination among staff and will use this input to inform our future measure development efforts. Finally, in relation to the commenter requesting us to remind the public that HCP vaccination is not mandatory, we assume that the commenter is recommending adding this reminder to the Care Compare web page. We appreciate the commenter's suggestion and will consider it when the modified HCP COVID–19 Vaccine measure is publicly reported on Care Compare.

Comment: One commenter opposed the measure's modified numerator definition because the FDA has not fully authorized the bivalent booster, rather it remains available under an Emergency Use Authorization (EUA).

Response: We note that, on August 31, 2022, the FDA amended the EUAs for the Moderna COVID–19 vaccine and the Pfizer-BioNTech COVID–19 vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination.[57] See more details in section VII.C.1.a.1. of this final rule. We would like to refer readers to the FDA website for additional information related to FDA process for evaluating an EUA request at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.* In addition, we emphasize that the FDA is closely monitoring the safety of the COVID–19 vaccines authorized for emergency use. We believe that due to the ongoing risk of infection transmissions in the SNF population, the benefits of finalizing the modified up to date definition of the measure in this year's final rule is essential for patient safety.

Comment: Several commenters opposed the proposed modifications to the HCP COVID–19 Vaccine measure, and the most frequently cited reason was that the COVID–19 PHE ended on May 11, 2023 and CMS subsequently lifted staff vaccination requirements established under § 483.80(i).[58] One commenter was concerned that the data reporting requirements associated with the measure will divert already stretched resources from resident care to administrative processes. Another commenter thought it was counter-intuitive for CMS to end vaccination mandates for HCP while seeking to amend the numerator for this measure. One commenter called for an elimination of the HCP COVID–19 Vaccine measure in the SNF QRP, while another commenter stated that they were comfortable with continuing to report on the measure during 2024 as the Administration and the broader healthcare ecosystem continue to assess what COVID–19 looks like moving forward. This commenter encouraged CMS to continue to evaluate and revisit the measure's requirements.

Response: We do not agree with commenters suggesting that because the PHE ended, and we lifted the staff vaccination requirements, that there is no value in retaining the HCP COVID–19 Vaccine measure in the SNF QRP.

[56] Pilishvili T, Gierke R, Fleming-Dutra KE, et al. Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. N Engl J Med. 2021 Dec 16;385(25):e90. doi: 10.1056/NEJMoa2106599. PMID: 34551224; PMCID: PMC8482809.

[57] Food and Drug Administration. Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. August 31, 2022. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.*

[58] On June 5, 2023, CMS issued the Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs–IID) to Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements final rule. This final rule withdrew the regulations in the interim final rule with comment (IFC) ''Omnibus COVID–19 Health Care Staff Vaccination'' published in the November 5, 2021 **Federal Register**.

We believe this measure continues to align with our goals to promote wellness and disease prevention. Under CMS' Meaningful Measures Framework 2.0, the HCP COVID–19 Vaccine measure addresses the quality priorities of ''Immunizations'' and ''Public Health'' through the Meaningful Measures Area of ' ''Wellness and Prevention.'' [59] Under the National Quality Strategy, the measure addresses the goal of Safety under the priority area Safety and Resiliency.[60] While the end of the PHE may result in removing vaccination requirements from the LTC Conditions of Participation, we note that the reporting requirements of the SNF QRP for the proposed modified version of the HCP COVID–19 Vaccine measure are distinct from those cited by the commenter. Specifically, the SNF QRP is a pay-for-reporting program, and therefore the inclusion of this measure in the SNF QRP does not require that HCP actually receive these booster vaccine doses in order for the SNF to successfully participate in the SNF QRP. Our continued response to COVID–19 is not fully dependent on the emergency declaration for the COVID–19 PHE, and even beyond the end of the COVID–19 PHE, we will continue to work to protect individuals and communities from the virus and its worst impacts by supporting access to COVID–19 vaccines, treatments, and tests.[61]

Comment: One additional commenter requested clarification on whether the White House's announcement to end COVID–19 vaccination requirements and/or ''mandates'' will impact the adoption or use of the proposed HCP COVID–19 Vaccine measure in the SNF QRP.

Response: We clarify that the vaccination requirements under § 483.80(i) (which have now been lifted) are separate from SNF QRP requirements to report HCP COVID–19 vaccination data. Even though the PHE has ended, and vaccination requirements have been lifted, CMS intends to encourage ongoing COVID–19 vaccination through use of its quality reporting programs (88 FR 36487). One way to encourage resident safety and COVID–19 vaccination is through adoption of the modified up to date numerator definition of the HCP COVID–19 Vaccine measure. Despite the White House's announcement,[62] the SNF QRP still requires data submission of the HCP COVID–19 Vaccine measure to the NHSN for SNFs to remain in compliance with the SNF QRP reporting requirements. However, since the SNF QRP is a pay-for-reporting program, HCP receiving COVID–19 vaccination is not mandated by this measure.

Comment: One commenter noted the proposed rule stated that data will be submitted through the Healthcare Personnel Safety (HPS) component of NHSN (88 FR 21337), and they point out that the data are actually submitted through the Long-Term Care Facility (LTCF) component as part of the SNF regulatorily required reporting.

Response: We thank the commenter and acknowledge that in the FY 2024 SNF PPS proposed rule (88 FR 21337), we incorrectly stated that SNFs would submit data to the NHSN HPS component. We clarify that, in alignment with the current version of the measure established in the FY 2022 SNF PPS final rule, SNFs will continue to submit HCP COVID–19 Vaccine data under this modified measure to the LTCF component of the CDC's NHSN before the quarterly deadline. We refer readers to section VII.C.1.a.4. of this final rule, where we have remediated this error.

Comment: One commenter questioned why CMS would delay the modification to the HCP COVID–19 Vaccine measure to 2025, rather than implementing it now. They stated a delay may prove unnecessary given the uncertain future of COVID–19 and the efficacy and availability of COVID–19 vaccines over time.

Response: We refer the commenter to section VII.C.1.a.4 of this final rule where we proposed SNFs would report individuals who are up to date beginning in quarter four of CY 2023. To clarify, data reported in CY 2023 comply with the requirements for the FY 2025 SNF QRP.

Comment: One commenter questioned why CMS has prioritized use of the NHSN over State-run Immunization Information Systems (IIS) for data reporting. This commenter noted that IIS are more robust and allow for greater clarity on vaccination status as healthcare professionals and individuals transition throughout the health care system.

Response: We did not propose to modify the method of data submission for the HCP COVID–19 Vaccine measure. As we stated in the FY 2022 SNF PPS Final Rule (86 FR 42494), we understand IIS to be confidential, population-based, computerized databases that record immunization doses administered by participating providers to persons residing within a given geopolitical area, but these systems are not standardized across all SNFs. HHS has an Immunization Information Systems Support Branch (IISSB) that facilitates the development, implementation, and acceptance of these systems, but they are overseen by the States and/or organizations who develop them. In the FY 2022 SNF PPS final rule (86 FR 42493), we adopted the use of the NHSN COVID–19 Modules for tracking HCP COVID–19 vaccination rates across all sites of service, including SNFs, because most of the state IIS do not include the information needed to calculate the HCP COVID–19 Vaccine measure. Since SNFs have successfully reported HCP COVID–19 vaccination rates since the measure's initial data submission period (October 1, 2021 through December 31, 2021), we will continue using the CDC's NHSN as the measure's data submission platform.

Comment: One commenter expressed concerns with the validity of any COVID–19 vaccination measure that uses self-reported data from SNFs and their HCP and encouraged CMS to develop data sources beyond those that are self-reported. This commenter recommends that CMS develop and implement auditing and penalty systems to detect and respond to inaccurate or falsified data.

Response: We emphasize that we currently implement multiple processes to ensure self-reported data are accurate. As part of our measure monitoring and compliance determination processes, we scrutinize provider data submission for all SNF QRP measures, including those for NHSN measures. We look for any performance gaps or discordant performance in measures that may indicate issues with data submission.

Comment: One commenter suggested that if the measure continues to be included in the SNF QRP, CMS should reduce the burden of gathering data from all personnel captured within the measure's denominator population.

[59] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. June 17, 2022Accessed May 26, 2023. *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.*

[60] Centers for Medicare & Medicaid Services. CMS National Quality Strategy. Accessed May 26, 2023. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/cms-quality-strategy.*

[61] U.S. Department of Health and Human Services. Fact Sheet: End of the COVID–19 Public Health Emergency. May 9, 2023. Accessed May 22, 2023. *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html.*

[62] White House. The Biden-Harris Administration Will End COVID–19 Vaccination Requirements for Federal Employees, Contractors, International Travelers, Head Start Educators, and CMS-Certified Facilities. May 1, 2023. *https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/01/the-biden-administration-will-end-covid-19-vaccination-requirements-for-federal-employees-contractors-international-travelers-head-start-educators-and-cms-certified-facilities/.*

Response: We did not propose changes to the measure denominator and disagree that the denominator criteria should be loosened. We emphasize that any HCP working in the facility for at least one working day during the reporting period, meeting denominator eligibility criteria, may come into contact with SNF residents, increasing the risk for HCP-to-resident transmission of infection. Therefore, we believe the measure as proposed has the potential to increase up to date COVID–19 vaccination coverage in SNFs, promote resident safety, and increase the transparency of quality of care in the SNF setting.

Comment: One commenter urged CMS to expand the criteria of HCP that are exempted beyond those with contraindications as defined by the CDC because there are numerous reasons HCP may decide whether to be up to date on vaccinations. One commenter specifically took issue with the measure's lack of religious exemptions. Another commenter was concerned that a SNF could be unfairly penalized for following CDC guidelines while delivering care that focuses on supporting individuals' ability to choose the recommended vaccine option that best suits their needs and preferences. This commenter suggested alignment of the HCP COVID–19 Vaccine measure's up to date definition with that of the Advisory Committee on Immunization Practices (ACIP) and recommended that the measure allow HCP to choose the vaccine option that best suits their needs and preferences.

Response: We acknowledge that numerous factors may impact an individual's decision to receive up to date vaccinations, such as sincerely held religious beliefs, observances, or practices. However, we emphasize that any HCP may come into contact with SNF residents, increasing the risk for HCP-to-resident transmission of infection. Therefore, we believe the measure as proposed has the potential to increase up to date HCP COVID–19 vaccination coverage in SNFs, promote resident safety, and increase the transparency of quality of care in the SNF setting. Additionally, we want to reiterate that neither the current version nor the proposed modified version of the measure mandate that HCP be up to date on their COVID–19 vaccine. The HCP COVID–19 Vaccine measure only requires reporting of vaccination rates for a SNF to successfully participate in the SNF QRP. Therefore, this measure is not preventing anyone from choosing a vaccine option that best suits their beliefs or preferences. In regard to the comment about aligning the measure's up to date definition with that of ACIP, the CDC's and ACIP's definitions are currently aligned. Additionally, we note that recommendations made by the ACIP are reviewed by the CDC and published as the official CDC recommendation if adopted.

Comment: One commenter stated that the CDC maintains guidance that receiving a dose of the COVID–19 vaccine may or should be delayed if a person has recently had the COVID–19 infection. This may impact the timing of an employee's up to date vaccine dosage.

Response: The CDC recommends that individuals who recently had a COVID–19 infection should still stay up to date with vaccines; however, individuals may consider delaying their next vaccine dose by three months from when (i) symptoms began, or (ii) initial receipt of a positive COVID–19 test. The CDC reiterates that certain factors could be reasons for individuals to receive up to date vaccinations sooner rather than later, including (i) personal risk of severe disease, (ii) risk of disease among close contacts, (iii) local COVID–19 hospital admission level, and (iv) the most common COVID–19 variant currently causing illness.[63] Since the CDC recommends that individuals stay up to date on vaccines regardless of recent COVID–19 infection, and since HCP often come into close contact with individuals at risk of disease, we do not agree that a recent COVID–19 infection would prevent HCP from receiving up to date COVID–19 vaccinations.

Comment: One commenter recommended that the measure should be revised to cover all CDC-recommended vaccines, and that the measure can be revised periodically as CDC guidance changes.

Response: We thank the commenter for this suggestion and will use this input to inform our future measure development efforts.

Comment: One commenter requested CMS mandate that all SNF HCP receive an up to date COVID–19 vaccination.

Response: Staff COVID–19 vaccination is no longer required under § 483.80(i). We continue to encourage ongoing COVID–19 vaccination through our quality reporting and value-based incentive programs. We emphasize that the proposed modifications to the HCP COVID–19 Vaccine measure for the SNF QRP do not mandate HCP COVID–19 vaccination.

Comment: Although generally supportive of the HCP COVID–19 Vaccine modifications to the up to date numerator definition, a few commenters recommended that CMS revise the measure to only require annual reporting, which would align with reporting requirements for the HCP Influenza Vaccine measure.

Response: As we stated in the FY 2024 SNF PPS proposed rule (88 FR 21336), the measure developer, the CDC, noted that the model used for this measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), and it intends to utilize a similar approach for the HCP COVID–19 Vaccine measure if the vaccination strategy becomes seasonal. We continue to monitor COVID–19 as part of our public health response and will consider these data to inform any potential action that may address seasonality in future rulemaking.

We also received comments related to the public reporting of the modified HCP COVID–19 Vaccine measure.

Comment: One commenter emphasized the importance of publicly reporting the HCP COVID–19 Vaccine measure on Care Compare, and recommended CMS coordinate public display of the HCP COVID–19 vaccine with existing measures of staff and resident COVID–19 vaccination and rates to avoid confusion or duplication. This commenter also suggested CMS include demographic information in the public display of the data in order to highlight potential disparities similar to those already uncovered about COVID–19 variation within facilities and among residents. Finally, this commenter stated CMS should give strong consideration to providing results to facilities that are stratified for race, ethnicity, and other social risk factors based on information submitted by facilities.

Response: We thank the commenter for their suggestions. However, as described in section VII.C.1.a.3. of this final rule, the measure developer (CDC) stated that the measure could not be stratified by demographic factors since the data are submitted at an aggregate rather than an individual level. We will continue to assess methods of incorporating health equity into the SNF QRP. In response to the commenter's recommendation to align the way in which measures of staff vaccination are presented on Care Compare, we appreciate this suggestion and will take it into consideration.

Comment: Several commenters were concerned with the delay between data submission via the NHSN and public reporting on Care Compare. One commenter emphasized that staff in SNFs may change over time so publicly

[63] Centers for Disease Control and Prevention. Stay Up to Date with COVID–19 Vaccines. July 17, 2023. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#UTD.*

reported measure data will become outdated quickly. Another commenter stated the delay between when the information is collected and when it is actually publicly reported could cause confusion and damage the public's trust and confidence in the quality of care delivered in their community if the rate of up to date HCP vaccination is low due to the data lag.

Response: We agree that it is important to make the most up to date data available to beneficiaries and ensure timely display of publicly reported data. Therefore, as mentioned in the FY 2022 SNF PPS final rule (86 FR 42496 through 42497), we revised our public reporting policy for this measure to use quarterly reporting, which allows the most recent quarter of data to be displayed, as opposed to an average of four rolling quarters. Additionally, the public display schedule of the HCP COVID–19 Vaccine measure aligns with SNF QRP public display policies finalized in the FY 2017 SNF PPS final rule (81 FR 52041), which allows SNFs to submit their SNF QRP data up to 4.5 months after the end of the reporting quarter. A number of administrative tasks must then occur in sequential order between the time SNF QRP data are submitted and reported in Care Compare to ensure the validity of data and to allow SNFs sufficient time to request a review of their data during the preview period if they believe the quality measure scores that are displayed within their Preview Reports are inaccurate. We believe this reporting schedule, outlined in section VII.C.1.a.4. of this final rule is reasonable, and expediting this schedule may establish undue burden on SNFs and jeopardize the integrity of the data.

Additionally, in response to the comment that staff in SNFs may change over time, we emphasize that it is precisely because staff in SNF's change that monitoring COVID–19 up to date vaccination rates over time is important.

Comment: One commenter pointed out that it may mean that HCPs who count as up to date in one quarter may no longer be up to date in the next quarter and CMS needs to clearly communicate what publicly reported data reflect.

Response: We agree with the commenter that pointed out that HCP who count as up to date in one quarter may no longer be up to date in the next quarter. We note that each provider will be measured against the same criteria within the same quarter, and the guideline for each quarter will be shared through the CDC's website ahead of each quarter. Regarding the data collection period used for public reporting, this information can be retrieved through the Care Compare site through ''View Quality Measures,'' and then clicking on ''Get current data collection period.''

Comment: One commenter noted that changing CDC definitions are challenging for healthcare professionals, and they do not believe that this information can be articulated in a manner for residents to fully digest in order to make meaningful healthcare decisions.

Response: We believe residents will be able to understand what changes to the up to date definition mean on Care Compare. We note that the public has been using the information displayed on Care Compare for the current HCP COVID–19 Vaccine measure since it was first publicly reported in 2022. We work closely with our Office of Communications and consumer groups when onboarding measures to the Care Compare websites, and we will do the same with the modified HCP COVID–19 Vaccine measure to ensure that the measure description on Care Compare is clear and understandable for the general public.

After careful consideration of the public comments we received, we are finalizing our proposal to modify the HCP COVID–19 Vaccine measure beginning with the FY 2025 SNF QRP as proposed.

b. Discharge Function Score Measure Beginning With the FY 2025 SNF QRP

(1) Background

SNFs provide short-term skilled nursing care and rehabilitation services, including physical and occupational therapy and speech-language pathology services. The most common resident conditions are septicemia, joint replacement, heart failure and shock, hip and femur procedures (not including major joint replacement), and pneumonia.[64] Septicemia progressing to sepsis is often associated with long-term functional deficits and increased mortality in survivors.[65] Rehabilitation of function, however, has been shown to be effective and is associated with reducing mortality and improving quality of life.[66] [67]

Section 1888(e)(6)(B)(i) of the Act, cross-referencing subsections (b), (c), and (d) of section 1899B of the Act, requires us to develop and implement standardized quality measures from five quality measure domains, including the domain of functional status, cognitive function, and changes in function and cognitive function across the post-acute care (PAC) settings, including SNFs. To satisfy this requirement, we adopted the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan) measure, for the SNF QRP in the FY 2016 SNF PPS final rule (80 FR 46444 through 46453). While this process measure allowed for the standardization of functional assessments across assessment instruments and facilitated cross-setting data collection, quality measurement, and interoperable data exchange, we believe it is now topped out and proposed to remove it in the FY 2024 SNF PPS proposed rule (88 FR 21342). While there are other outcome measures addressing functional status [68] that can reliably distinguish performance among providers in the SNF QRP, these outcome measures are not cross-setting in nature because they rely on functional status items not collected in all PAC settings. In contrast, a cross-setting functional outcome measure would align measure specifications across settings, including the use of a common set of standardized functional assessment data elements.

(a) Measure Importance

Maintenance or improvement of physical function among older adults is increasingly an important focus of health care. Adults age 65 years and

[64] Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. June 2021. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf*.

[65] Winkler D, Rose N, Freytag A, Sauter W, Spoden M, Schettler A, Wedekind L, Storch J, Ditscheid B, Schlattmann P, Reinhart K, Günster C, Hartog CS, Fleischmann-Struzek C. The Effect of Post-acute Rehabilitation on Mortality, Chronic Care Dependency, Health Care Use and Costs in Sepsis Survivors. Ann Am Thorac Soc. 2022 Oct 17. doi: 10.1513/AnnalsATS.202203–195OC. Epub ahead of print. PMID: 36251451.

[66] Chao PW, Shih CJ, Lee YJ, Tseng CM, Kuo SC, Shih YN, Chou KT, Tarng DC, Li SY, Ou SM, Chen YT. Association of Post discharge Rehabilitation with Mortality in Intensive Care Unit Survivors of Sepsis. Am J Respir Crit Care Med. 2014 Nov 1;190(9):1003–11. doi: 10.1164/rccm.201406–1170OC. PMID: 25210792.

[67] Taito S, Taito M, Banno M, Tsujimoto H, Kataoka Y, Tsujimoto Y. Rehabilitation for Patients with Sepsis: A Systematic Review and Meta-Analysis. PLoS One. 2018 Jul 26;13(7):e0201292. doi: 10.1371/journal.pone.0201292. Erratum in: PLoS One. 2019 Aug 21;14(8):e0221224. PMID: 30048540; PMCID: PMC6062068.

[68] The measures include: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients, IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients, IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients, IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.

older constitute the most rapidly growing population in the United States, and functional capacity in physical (non-psychological) domains has been shown to decline with age.[69] Moreover, impaired functional capacity is associated with poorer quality of life and an increased risk of all-cause mortality, postoperative complications, and cognitive impairment, the latter of which can complicate the return of a resident to the community from post-acute care.[70 71 72] Nonetheless, evidence suggests that physical functional abilities, including mobility and self-care, are modifiable predictors of resident outcomes across PAC settings, including functional recovery or decline after post-acute care,[73 74 75 76 77] rehospitalization rates,[78 79 80] discharge to community,[81 82] and falls.[83]

The implementation of interventions that improve residents' functional outcomes and reduce the risks of associated undesirable outcomes as a part of a resident-centered care plan is essential to maximizing functional improvement. For many people, the overall goals of SNF care may include optimizing functional improvement, returning to a previous level of independence, maintaining functional abilities, or avoiding institutionalization. Studies have suggested that rehabilitation services provided in SNFs can improve residents' mobility and functional independence for residents with various diagnoses, including cardiovascular and pulmonary conditions, orthopedic conditions, and stroke.[84 85] Moreover, studies found an association between the level of therapy intensity and better functional improvement, suggesting that assessment of functional status as a health outcome in SNFs can provide valuable information in determining treatment decisions throughout the care continuum, such as the need for rehabilitation services, and discharge planning,[86 87 88] as well as provide information to consumers about the effectiveness of skilled nursing services and rehabilitation services delivered. Because evidence shows that older adults experience aging heterogeneously and require individualized and comprehensive health care, functional status can serve as a vital component in informing the provision of health care and thus indicate a SNF's quality of care.[89 90]

We proposed to adopt the Discharge Function Score (DC Function) measure [91] in the SNF QRP beginning with the FY 2025 SNF QRP. This assessment-based outcome measure evaluates functional status by calculating the percentage of Medicare Part A SNF residents who meet or

[69] High KP, Zieman S, Gurwitz J, Hill C, Lai J, Robinson T, Schonberg M, Whitson H. Use of Functional Assessment to Define Therapeutic Goals and Treatment. J Am Geriatr Soc. 2019 Sep;67(9):1782–1790. doi: 10.1111/jgs.15975. Epub 2019 May 13. PMID: 31081938; PMCID: PMC6955596.

[70] Clouston SA, Brewster P, Kuh D, Richards M, Cooper R, Hardy R, Rubin MS, Hofer SM. The dynamic relationship between physical function and cognition in longitudinal aging cohorts. Epidemiol Rev. 2013;35(1):33–50. doi: 10.1093/epirev/mxs004. Epub 2013 Jan 24. PMID: 23349427; PMCID: PMC3578448.

[71] Michael YL, Colditz GA, Coakley E, Kawachi I. Health behaviors, social networks, and healthy aging: cross-sectional evidence from the Nurses' Health Study. Qual Life Res. 1999 Dec;8(8):711–22. doi: 10.1023/a:1008949428041. PMID: 10855345.

[72] High KP, Zieman S, Gurwitz J, Hill C, Lai J, Robinson T, Schonberg M, Whitson H. Use of Functional Assessment to Define Therapeutic Goals and Treatment. J Am Geriatr Soc. 2019 Sep;67(9):1782–1790. doi: 10.1111/jgs.15975. Epub 2019 May 13. PMID: 31081938; PMCID: PMC6955596.

[73] Deutsch A, Palmer L, Vaughan M, Schwartz C, McMullen T. Inpatient Rehabilitation Facility Patients' Functional Abilities and Validity Evaluation of the Standardized Self-Care and Mobility Data Elements. Arch Phys Med Rehabil. 2022 Feb 11:S0003–9993(22)00205–2. doi: 10.1016/j.apmr.2022.01.147. Epub ahead of print. PMID: 35157893.

[74] Hong I, Goodwin JS, Reistetter TA, Kuo YF, Mallinson T, Karmarkar A, Lin YL, Ottenbacher KJ. Comparison of Functional Status Improvements Among Patients With Stroke Receiving Postacute Care in Inpatient Rehabilitation vs Skilled Nursing Facilities. JAMA Netw Open. 2019 Dec 2;2(12):e1916646. doi: 10.1001/jamanetworkopen.2019.16646. PMID: 31800069; PMCID: PMC6902754.

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[77] Lane NE, Stukel TA, Boyd CM, Wodchis WP. Long-Term Care Residents' Geriatric Syndromes at Admission and Disablement Over Time: An Observational Cohort Study. J Gerontol A Biol Sci Med Sci. 2019;74(6):917–923. doi:10.1093/gerona/gly151. PMID: 29955879; PMCID: PMC6521919.

[78] Li CY, Haas A, Pritchard KT, Karmarkar A, Kuo YF, Hreha K, Ottenbacher KJ. Functional Status Across Post-Acute Settings is Associated With 30-Day and 90-Day Hospital Readmissions. J Am Med Dir Assoc. 2021 Dec;22(12):2447–2453.e5. doi: 10.1016/j.jamda.2021.07.039. Epub 2021 Aug 30. PMID: 34473961; PMCID: PMC8627458.

[79] Middleton A, Graham JE, Lin YL, Goodwin JS, Bettger JP, Deutsch A, Ottenbacher KJ. Motor and Cognitive Functional Status Are Associated with 30-day Unplanned Rehospitalization Following Post-Acute Care in Medicare Fee-for-Service Beneficiaries. J Gen Intern Med. 2016 Dec;31(12):1427–1434. doi: 10.1007/s11606–016–3704–4. Epub 2016 Jul 20. PMID: 27439979; PMCID: PMC5130938.

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[91] This measure was submitted to the Measures Under Consideration (MUC) List as the Cross-Setting Discharge Function Score. Subsequent to the MAP workgroup meetings, CMS modified the name. For more information, refer to the Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

exceed an expected discharge function score. We also proposed to replace the topped-out Application of Functional Assessment/Care Plan process measure with the DC Function measure. Like the cross-setting process measure we proposed to remove in the FY 2024 SNF PPS proposed rule (88 FR 21342), the DC Function measure is calculated using standardized resident assessment data from the current SNF assessment tool, the Minimum Data Set (MDS).

The DC Function measure supports our current priorities. Specifically, the measure aligns with the Streamline Quality Measurement domain in CMS's Meaningful Measurement 2.0 Framework in two ways. First, the proposed outcome measure would further our objective to prioritize outcome measures by replacing the current cross-setting process measure (see FY 2024 SNF PPS proposed rule 88 FR 21342). This proposed DC Function measure uses a set of cross-setting assessment items which would facilitate data collection, quality measurement, outcome comparison, and interoperable data exchange among PAC settings; existing functional outcome measures do not use a set of cross-setting assessment items. Second, this measure would add no additional provider burden since it would be calculated using data from the MDS that SNFs are already required to collect.

The proposed DC Function measure also follows a calculation approach similar to the existing functional outcome measures, which are CBE endorsed, with some modifications.[92] Specifically, the measure (1) considers two dimensions of function (self-care and mobility activities) and (2) accounts for missing data by using statistical imputation to improve the validity of measure performance. The statistical imputation approach recodes missing functional status data to the *most likely value* had the status been assessed, whereas the current imputation approach implemented in existing functional outcome measures recodes missing data to the *lowest* functional status. A benefit of statistical imputation is that it uses resident characteristics to produce an unbiased estimate of the score on each item with a missing value. In contrast, the current approach treats residents with missing values and residents who were coded to the lowest functional status similarly, despite evidence suggesting varying measure performance between the two groups, which can to lead less accurate measure performances.

(b) Measure Testing

Our measure developer conducted testing using FY 2019 data on the DC Function measure to assess validity, reliability, and reportability, all of which informed interested parties' feedback and Technical Expert Panel (TEP) input (see FY 2024 SNF PPS proposed rule 88 FR 21340 through 21341). Validity was assessed for the measure performance, the risk adjustment model, face validity, and statistical imputation models. Validity testing of measure performance entailed determining Spearman's rank correlations between the proposed measure's performance for providers with 20 or more stays and the performance of other publicly reported SNF quality measures. Results indicated that the measure captures the intended outcome based on the directionalities and strengths of correlation coefficients and are further detailed below in Table 12.

TABLE 12—SPEARMAN'S RANK CORRELATION RESULTS OF DC FUNCTION MEASURE WITH PUBLICLY REPORTED SNF QUALITY MEASURES

Measure—long name	Measure—short name	ρ
Discharge to Community—PAC SNF QRP	Discharge to Community	0.16
Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients.	Change in Self-Care Score	0.75
Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients.	Change in Mobility Score	0.78
Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients.	Discharge Self-Care Score	0.78
Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.	Discharge Mobility Score	0.80
Potentially Preventable 30-Day Post-Discharge Readmission Measure—SNF QRP.	Potentially Preventable Readmissions within 30 Days Post-Discharge.	−0.10
Medicare Spending Per Beneficiary—PAC SNF QRP	Medicare Spending Per Beneficiary	−0.07

Validity testing of the risk adjustment model showed good model discrimination as the measure model has the predictive ability to distinguish residents with low expected functional capabilities from those with high expected functional capabilities.[93] The ratios of observed-to-predicted discharge function score across eligible stays, by deciles of expected functional capabilities, ranged from 0.99 to 1.01. Both the Cross-Setting Discharge Function TEPs and resident-family feedback showed strong support for the face validity and importance of the proposed measure as an indicator of quality of care (see FY 2024 SNF PPS proposed rule 88 FR 21340 through 21341). Lastly, validity testing of the measure's statistical imputation models indicated that the models demonstrate good discrimination and produce more precise and accurate estimates of function scores for items with missing scores when compared to the current imputation approach implemented in SNF QRP functional outcome measures, specifically the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients measure (Change in Self-Care Score), the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients measure (Change in Mobility Score), the Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients measure (Discharge Self-Care Score), and the Application of IRF Functional Outcome Measure: Discharge Mobility Score for

[92] The existing measures are the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients measure (Discharge Self-Care Score), and the Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients measure (Discharge Mobility Score).

[93] "Expected functional capabilities" is defined as the predicted discharge function score.

Medical Rehabilitation Patients measure (Discharge Mobility Score) measures.

Reliability and reportability testing also yielded results that support the measure's scientific acceptability. Split-half testing revealed the proposed measure's good reliability, indicated by an intraclass correlation coefficient value of 0.81. Reportability testing indicated high reportability (85 percent) of SNFs meeting the public reporting threshold of 20 eligible stays. For additional measure testing details, we refer readers to the document titled *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report.*[94]

(2) Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act be endorsed by the CBE with a contract under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed DC Function measure is not CBE endorsed, so we considered whether there are other available measures that: (1) assess both functional domains of self-care and mobility in SNFs and (2) satisfy the requirement of the Act to specify quality measures with respect to functional status, cognitive function, and changes in function and cognitive function across the PAC settings. While the Application of Functional Assessment/Care Plan measure assesses both functional domains and satisfies the Act's requirement, this cross-setting process measure is not CBE endorsed and the measure's performance among SNFs is so high and unvarying across most SNFs that the measure no longer offers meaningful distinctions in performance. Additionally, after review of other measures endorsed or adopted by a consensus organization, we were unable to identify any measures endorsed or adopted by a consensus organization for SNFs that meet the aforementioned requirements. While the SNF QRP includes CBE endorsed outcome measures addressing functional status,[95] they each assess a single domain of function, and are not cross-setting in nature because they rely on functional status items not collected in all PAC settings.

Therefore, after consideration of other available measures, we find that the exception under section 1899B(e)(2)(B) of the Act applies and proposed to adopt the DC Function measure, beginning with the FY 2025 SNF QRP. We intend to submit the proposed measure to the CBE for consideration of endorsement when feasible.

(3) Interested Parties and Technical Expert Panel (TEP) Input

In our development and specification of this measure, we employed a transparent process in which we sought input from interested parties and national experts and engaged in a process that allowed for pre-rulemaking input, in accordance with section 1890A of the Act. To meet this requirement, we provided the following opportunities for input from interested parties: a focus group of patient and family/caregiver advocates (PFAs), two TEPs, and public comments through a request for information (RFI).

First, the measure development contractor convened a PFA focus group, during which residents and caregivers provided support for the proposed measure concept. Participants emphasized the importance of measuring functional outcomes and found self-care and mobility to be critical aspects of care. Additionally, they expressed an interest in measures assessing the number of residents discharged from particular facilities with improvements in self-care and mobility, and their views of self-care and mobility aligned with the functional domains captured by the proposed measure. All feedback was used to inform measure development efforts.

The measure development contractor for the DC Function measure subsequently convened TEPs on July 14 to 15, 2021 and January 26 to 27, 2022 to obtain expert input on the development of a cross-setting function measure for use in the SNF QRP. The TEPs consisted of interested parties with a diverse range of expertise, including SNF and PAC subject matter knowledge, clinical expertise, resident and family perspectives, and measure development experience. The TEPs supported the proposed measure concept and provided substantive feedback regarding the measure's specifications and measure testing data.

First, the TEP was asked whether they prefer a cross-setting measure that is modeled after the currently adopted Discharge Mobility Score and Discharge Self-Care Score measures, or one that is modeled after the currently adopted Change in Mobility Score and Change in Self-Care Score measures. With the Discharge Mobility Score and Change in Mobility Score measures and the Discharge Self-Care Score and Change in Self-Care Score measures being both highly correlated and not appearing to measure unique concepts, the TEP favored the Discharge Mobility Score and Discharge Self-Care Score measures over the Change in Mobility Score and Change in Self-Care Score measures and recommended moving forward with utilizing the Discharge Mobility Score and Discharge Self-Care Score measures' concepts for the development of a cross-setting measure.

Second, in deciding the standardized functional assessment data elements to include in the cross-setting measure, the TEP recommended removing redundant data elements. Strong correlations between scores of functional items within the same functional domain suggested that certain items may be redundant in eliciting information about resident function and inclusion of these items could lead to overrepresentation of a particular functional area. Subsequently, our measure development contractor focused on the Discharge Mobility Score measure as a starting point for cross-setting development due to the greater number of cross-setting standardized functional assessment data elements for mobility while also identifying redundant functional items that could be removed from a cross-setting functional measure.

Third, the TEP supported including the cross-setting self-care items such that the cross-setting function measure would capture both self-care and mobility. Panelists agreed that self-care items added value to the measure and are clinically important to function. Lastly, the TEP provided refinements to imputation strategies to more accurately represent functional performance across all PAC settings, including the support of using statistical imputation over the current imputation approach implemented in existing functional outcome measures in the PAC QRPs. We considered all recommendations from the TEPs and we applied their recommendations where technically feasible and appropriate. Summaries of

[94] *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

[95] The measures include: Change in Self-Care Score for Medical Rehabilitation Patients (CBE #2633), Change in Mobility for Medical Rehabilitation Patients (CBE #2634), Discharge Self-Care Score for Medical Rehabilitation Patients (CBE #2635), Discharge Mobility Score for Medical Rehabilitation Patients (CBE #2636).

the TEP proceedings titled *Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report* (July 2021 TEP) [96] and *Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report* (January 2022 TEP) [97] are available on the CMS Measures Management System (MMS) Hub.

Finally, we solicited feedback from interested parties on the importance, relevance, and applicability of a cross-setting functional outcome measure for SNFs through an RFI in the FY 2023 SNF PPS proposed rule (87 FR 22754). Commenters were supportive of a cross-setting functional outcome measure that is inclusive of both self-care and mobility items, but also provided information related to potential risk-adjustment methodologies, as well as other measures that could be used to capture functional outcomes across PAC settings (87 FR 47553).

(4) Measure Applications Partnership (MAP) Review

In accordance with section 1890A of the Act, our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List, that the Secretary is considering adopting for use in Medicare programs. This allows interested parties to provide recommendations to the Secretary on the measures included on the list.

We included the DC Function measure under the SNF QRP in the publicly available MUC List for December 1, 2022.[98] After the MUC List was published, the CBE convened MAP received three comments from interested parties in the industry on the 2022 MUC List. Two commenters were supportive of the measure and one was not. Among the commenters in support of the measure, one commenter stated that function scores are the most meaningful outcome measure in the SNF setting, as they not only assess resident outcomes but also can be used for clinical improvement processes. Additionally, this commenter noted the measure's good reliability and validity and that the measure is feasible to implement. The second commenter noted that the DC Function measure is modeled on an CBE endorsed measure and has undergone an extensive formal development process. In addition, the second commenter noted that the DC Function measure improves on the existing functional outcome measures and recommended replacing the existing function measures with the DC Function measure.

One commenter did not support the DC Function measure and raised the following concerns: the ''gameability'' of the expected discharge score, the measure's complexity, and the difficulty of implementing a composite functional score.

Shortly after, several CBE convened MAP workgroups met to provide input on the DC Function measure. First, the MAP Health Equity Advisory Group convened on December 6 to 7, 2022. The MAP Health Equity Advisory Group did not share any health equity concerns related to the implementation of the DC Function measure, and only requested clarification regarding measure specifications from the measure steward. The MAP Rural Health Advisory Group met on December 8 to 9, 2022, during which some of the group's members provided support for the DC Function measure and other group members did not express rural health concerns regarding the DC Function measure.

The MAP PAC/LTC workgroup met on December 12, 2022 and provided input on the proposed DC Function measure. During this meeting, we were able to address several concerns raised by interested parties after the publication of the MUC List. Specifically, we clarified that the expected discharge scores are not calculated using self-reported functional goals, and are simply calculated by risk-adjusting the observed discharge scores (see FY 2024 SNF PPS proposed rule 88 FR 21342). Therefore, we believe that these scores cannot be ''gamed'' by reporting less-ambitious functional goals. We also pointed out that the measure is highly usable as it is similar in design and complexity to existing function measures and that the data elements used in this measure are already in use on the MDS submitted by SNFs. Lastly, we clarified that the DC Function measure is intended to supplement, rather than replace, existing SNF QRP measures for self-care and mobility and implements improvements on the existing Discharge Self-Care Score and Discharge Mobility Score measures that make the measure more valid and harder to game.

The MAP PAC/LTC workgroup went on to discuss other concerns with the DC Function measure, including (1) whether the measure is cross-setting due to denominator populations that differ among settings, (2) whether the measure would adequately represent the full picture of function, especially for residents who may have a limited potential for functional gain, and (3) that the range of expected scores was too large to offer a valid facility-level score. We clarified that the denominator population in each measure setting represents the assessed population within the setting and that the measure satisfies the requirement of section 1888(e)(6) of the Act for a cross-setting measure in the functional status domain specified under section 1899B(c)(1) of the Act. Additionally, we noted that the TEP had reviewed the item set and determined that all the self-care and mobility items were suitable for all settings. Further, we clarified that, because the DC Function measure would assess whether a resident met *or* exceeded their expected discharge score, it accounts for residents who are not expected to improve. Lastly, we noted that the DC Function measure has a high degree of correlation with the existing function measures and that the range of expected scores is consistent with the range of observed scores. The PAC/LTC workgroup voted to support the CBE staff recommendation of conditional support for rulemaking, with the condition that we seek CBE endorsement.

In response to the PAC/LTC workgroup's preliminary recommendation, the CBE received two more comments supporting the recommendation and one comment that did not. Among the commenters in support of the DC Function measure, one supported the measure under the condition that it be reviewed and refined such that its implementation supports resident autonomy and results in care that aligns with residents' personal functional goals. The second commenter supported the DC Function measure under the condition that it produces statistically meaningful information that can inform improvements in care processes. This commenter also expressed concern that the DC Function measure is not truly cross-setting because it utilizes different resident populations and risk-

[96] *Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report* (July 2021 TEP). *https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

[97] *Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report* (January 2022 TEP). *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf.*

[98] Centers for Medicare & Medicaid Services. Overview of the List of Measures Under Consideration for December 1, 2022. *CMS.gov. https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf.*

adjustment models with setting-specific covariates across settings. Additionally, this commenter noted that using a single set of cross-setting section GG items is not appropriate since the items in our standardized patient/resident assessment data instruments may not be relevant across varying resident-setting populations. The commenter who did not support the DC Function measure raised concern with the usability of a composite functional score for improving functional performance, and expressed support for using individual measures, such as the current Change in Mobility Score and Change in Self-Care Score measures, to attain this goal.

Finally, the MAP Coordinating Committee convened on January 24 to 25, 2023, during which the CBE received one comment not in support of the PAC/LTC workgroup's preliminary recommendation for conditional support of the DC Function measure. The commenter expressed concern that the DC Function measure competes with existing self-care and mobility measures in the SNF QRP. We noted that we monitor measures to determine if they meet any of the measure removal factors, set forth in § 413.360(b)(2), and when identified, we may remove such measure(s) through the rulemaking process. We noted again that the TEP had reviewed the item set and determined that all self-care and mobility items were suitable for all settings. The MAP Coordinating Committee members expressed support for reviewing existing measures for removal as well as support for the DC Function measure, favoring the implementation of a single, standardized function measure across PAC settings. The MAP Coordinating Committee unanimously upheld the PAC/LTC workgroup recommendation of conditional support for rulemaking. We refer readers to the final MAP recommendations, titled *2022–2023 MAP Final Recommendations.*[99]

(5) Quality Measure Calculation

The proposed DC Function measure is an outcome measure that estimates the percentage of Medicare Part A SNF residents who meet or exceed an expected discharge score during the reporting period. The proposed DC Function measure's numerator is the number of SNF stays with an observed discharge function score that is equal to or greater than the calculated expected discharge function score. The observed discharge function score is the sum of individual function items values at discharge. The expected discharge function score is computed by risk-adjusting the observed discharge function score for each SNF stay. Risk adjustment controls for resident characteristics such as admission function score, age, and clinical conditions. The denominator is the total number of SNF stays with an MDS record in the measure target period (four rolling quarters) that do not meet the measure exclusion criteria. For additional details regarding the numerator, denominator, risk adjustment, and exclusion criteria, refer to the *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report.*[100]

The proposed measure implements a statistical imputation approach for handling ''missing'' standardized functional assessment data elements. The coding guidance for standardized functional assessment data elements allows for using ''Activity Not Attempted'' (ANA) codes, resulting in ''missing'' information about a resident's functional ability on at least some items, at admission and/or discharge, for a substantive portion of SNF residents. Currently, functional outcome measures in the SNF QRP use a simple imputation method whereby all ANA codes or otherwise missing scores, on both admission and discharge records, are recoded to ''1'' or ''most dependent.'' Statistical imputation, on the other hand, replaces these missing values with a variable based on the values of other, non-missing variables in the assessment and on the values of other assessments which are otherwise similar to the assessment with a missing value. Specifically, the proposed DC Function measure's statistical imputation allows missing values (for example, the ANA codes) to be replaced with any value from 1 to 6, based on a resident's clinical characteristics and codes assigned on other standardized functional assessment data elements. The measure implements separate imputation models for each standardized functional assessment data element used in the construction of the discharge score and the admission score. Relative to the current simple imputation method, this statistical imputation approach increases precision and accuracy and reduces the bias in estimates of missing item values. We refer readers to the *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report* [101] for measure specifications and additional details.

We solicited public comment on our proposal to adopt the Discharge Function Score measure beginning with the FY 2025 SNF QRP. We received a number of comments from interested parties who support the adoption of the proposed measure, and others who supported the concept but encouraged CMS to continue to evaluate the methodology for validity. However, many commenters did not support the proposed measure for various reasons, including the lack of CBE endorsement, the concern that the methodology was replacing clinical judgement, and concerns around how the expected scores were calculated. The following is a summary of the comments we received on our proposal to adopt the DC Function measure, beginning with the FY 2025 SNF QRP, and our responses.

Comment: Several commenters supported the adoption of the proposed measure. Some of these commenters specifically noted that the statistical imputation approach is an improvement over the current imputation approach used in the functional outcome measures already in the SNF QRP.

Response: We thank commenters for their support of the adoption of the DC Function measure and agree that the statistical imputation approach improves upon the approach used in the measures currently in the SNF QRP.

Comment: One commenter who supported the addition of the DC Function measure encouraged continual evaluation of the imputation methodology for validity and any unintended negative consequences.

Response: We reevaluate measures implemented in the SNF QRP on an ongoing basis to ensure they have strong scientific acceptability and appropriately capture the care provided by SNFs. This monitoring includes the appropriateness and performance of both the risk models and imputation models used to calculate the measure.

Comment: One commenter agreed with the proposed statistical imputation approach utilized in the DC Function measure but suggested it might lead to confusion. Specifically, this commenter noted that the statistical imputation approach is only proposed for the DC Function measure and is not used for the Discharge Self-Care Score and Discharge Mobility Score measures,

[99] 2022–2023 MAP Final Recommendations. *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

[100] *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

[101] *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

despite the measures being similar. The commenter stated the different approaches may lead to different outcome percentages when looking at the Discharge Self-Care Score and Discharge Mobility Score measures and the DC Function measure.

Response: We thank the commenter for their support of the proposed statistical imputation approach utilized in the DC Function measure. We acknowledge the value of implementing this imputation approach in other measures using section GG items in the MDS, as measure testing has shown that this approach improves the validity of the DC Function measure over the current imputation approach used in existing measures in the SNF QRP. Measures undergo testing and refinement during measure development and maintenance activities, and we will consider testing the statistical imputation methodology in existing and future measures.

The DC Function measure captures information that is distinct from the Discharge Self-Care Score and Discharge Mobility Score measures. Specifically, the DC Function measure considers both dimensions of function (utilizing a subset of self-care and mobility GG items), while the Discharge Self-Care Score and Discharge Mobility Score measures each consider one dimension of function (utilizing all self-care and mobility GG items, respectively). For these same reasons, we expect to see differences in outcome percentages among these three measures for reasons unrelated to the imputation approach.

Comment: Four commenters did not support the adoption of this measure specifically because it lacks CBE endorsement or has not undergone the CBE endorsement process. Two of these commenters noted that the CBE endorsement process provides information on whether the measure provides valuable information that can be used to inform improvements in care.

Response: We direct readers to section VII.C.1.b.2. of this final rule, where we discuss this topic in detail. Despite the current absence of CBE endorsement for this measure, we still believe it is important to adopt the DC Function measure into the SNF QRP because, unlike the Discharge Self-Care Score and Discharge Mobility Score measures, the DC Function measure relies on functional status items collected in all PAC settings, satisfies the requirement of a cross-setting quality measure set forth in sections 1888(e)(6)(B)(i)(II) and 1899B(c)(1)(A) of the Act, and assesses both domains of function. We also direct readers to section VII.C.1.b.1. of this final rule, where we discuss measurement gaps that the DC function measure fulfills in relation to competing and related measures. We also acknowledge the importance of the CBE endorsement process and plan to submit the proposed measure for CBE endorsement in the future. We direct readers to section VII.C.1.b.3. of this final rule and the technical report for detailed measures testing results demonstrating that the measure provides meaningful information which can be used to improve quality of care, and to the TEP report summaries [102] [103] which detail TEP support for the proposed measure concept.

Comment: One commenter opposed the adoption of the DC Function measure due to concern with the proposed imputation approach. This commenter noted that the ''Activity Not Attempted'' codes allow clinicians to use their professional judgement when certain activities should not or could not be safely attempted by the resident, which may be due to medical reasons. Moreover, this commenter stated that among some residents not able to attempt certain self-care and mobility tasks at the time of admission, the use of ANA codes decreases significantly at the time of discharge, which they believe reflects the functional outcomes achieved during their SNF stay. With these considerations in mind, this commenter does not believe it is appropriate or accurate for CMS to override the clinical judgement of the clinicians who are treating the resident by using statistical imputation to impute a value to a data element where an ANA code was entered. Lastly, the commenter recommended that CMS engage with post-acute care clinicians to address their concerns that ANA codes are not truly reflective of residents' functional abilities and/or deficits.

Response: We acknowledge that the ''Activity Not Attempted'' (ANA) codes allow clinicians to use their professional judgement when certain activities should not or could not be safely attempted by the resident and that there may be medical reasons that a resident cannot safely attempt a task. However, we want to clarify that utilizing statistical imputation does not override the clinical judgement of clinicians who are expected to continue determining whether certain activities can be safely attempted by the residents when completing the MDS and utilizing the assessment data to determine appropriate goals for SNF residents. Rather, statistical imputation is a component in measure calculation of reported data and improves upon the imputation approach currently adopted in the Discharge Self-Care Score, Discharge Mobility Score, Change in Self-Care Score, and Change in Mobility Score measures by improving measure component validity.

In the Discharge Self-Care Score, Discharge Mobility Score, Change in Self-Care Score, and Change in Mobility Score measures, ANA codes are imputed to 1 (dependent) when calculating the measure scores, regardless of a resident's own clinical and functional information. The imputation approach implemented in the proposed DC Function measure uses each resident's available functional and clinical information to estimate each ANA value had the item been completed. Testing demonstrates that, relative to the current simple imputation method, the statistical imputation approach used in the DC Function measure increases precision and accuracy and reduces bias in estimates of missing item values.

Finally, in regard to the commenter's recommendation that we engage with PAC clinicians about the ANA codes, we have engaged with PAC clinicians on more than one occasion. As described in section VII.C.1.b.3. of this final rule, our measure development contractor convened two TEPs to obtain expert clinician input on the development of the measure. The TEPs consisted of interested parties with a diverse range of expertise, including SNF and other subject matter knowledge and clinical expertise, and measure development experience in PAC settings. As described in the PAC QRP Functions TEP Summary Report—March 2022,[104] panelists agreed that the recode approach used in the already adopted functional outcome measures could be improved upon and reiterated that not all ANAs reflect dependence on a function activity. Based on the extensive testing results presented to the TEP, a majority of panelists favored the statistical imputation over alternative

[102] Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report (July 2021 TEP). *https://mms-test.battelle.org/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

[103] Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report (January 2022 TEP). *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf.*

[104] Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report. Page 20. *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf.*

methodologies and an imputation method that is more accurate.

Comment: One commenter expressed concern with the proposed statistical imputation approach utilized in the DC Function measure and suggested it might lead to this measure score varying significantly from the Discharge Self-Care Score and Discharge Mobility Score measures' scores.

Response: The DC Function measure captures information that is distinct from the Discharge Self-Care Score and Discharge Mobility Score measures. Specifically, the DC Function measure considers both dimensions of function (utilizing a subset of self-care and mobility GG items in the MDS), while the Discharge Self-Care Score and Discharge Mobility Score measures each consider one dimension of function (utilizing all self-care and mobility GG items, respectively). For these same reasons, we expect to see differences in outcome percentages among these three measures for reasons unrelated to the imputation approach used.

Comment: Three commenters believe the measure's imputation and risk-adjustment approach are complex and difficult to understand. One of these commenters urged CMS to continuously evaluate the imputation method and its impact across the PAC settings and urged CMS to provide additional coding guidance for ANA use for the GG items in order to better standardize and reduce the use of ANA codes. The other two commenters suggested that CMS provide greater transparency on the ''expected'' discharge function score and/or the imputation method.

Response: The proposed measure uses imputation methods that are similar in complexity to the CBE endorsed functional outcome measures that have been in the SNF QRP for several years, and will be similarly specified. As such, interpreting measure performance should be no more difficult than understanding current functional outcome measures. We appreciate that statistical imputation adds additional steps to the measure's calculation; however, understanding the technical details of imputation and, separately, the construction of the expected scores, is not needed to correctly interpret the measure scores. For those who are interested in the technical details, the methodology and specifications are available in the *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report.*[105] As with all other measures, we will routinely monitor this measure's performance, including the statistical imputation approach, to ensure the measure remains valid and reliable. Finally, we would like to clarify that the adoption of this measure does not change how SNFs should complete the GG items. As stated in the MDS Resident Assessment Instrument (RAI) Manual, the ANA codes should only be used if the activity did not occur; that is, the resident did not perform the activity and a helper did not perform that activity for the resident. However, we acknowledge that there will be instances where an ANA code is the most appropriate code to select. We regularly review and update the manual as indicated. Additionally, if SNFs have questions related to the completion of these items, they can submit questions to the SNF QRP Help Desk at *SNFQualityQuestions@CMS.hhs.gov*.

Comment: Four commenters oppose the adoption of the proposed measure due to their doubt regarding the cross-setting applicability of the measure given the different resident populations served by the various PAC settings and pointed out that the capabilities and goals of residents differ widely by setting. One of these commenters stated that the measure is only ''cross-setting'' in name and that while the measure attempts to take into account the myriad of differences in the resident populations across settings, the DC Function measure is nevertheless four different measures across four different settings because the differences in resident populations alter the underlying calculation of the cross-setting measure. Three other commenters referenced the Therapy Outcomes in Post-Acute Care Settings study, which found significant differences in function across settings, which dictate differences in treatment.

Response: We acknowledge that different resident populations are served across the PAC settings and the capabilities and goals of these populations differ. However, we would like to clarify that cross-setting measures do not necessarily suggest that facilities can and should be compared across settings. Instead, these measures are intended to compare providers within a specific setting while standardizing measure specifications across settings. The proposed measure does just this, by aligning measure specifications across settings and using a common set of standardized functional assessment data elements.

Comment: Three commenters opposed the proposed DC Function measure because it combines self-care and mobility items from the MDS. Two commenters expressed a preference towards the Discharge Self-Care Score and Discharge Mobility Score measures currently adopted in the SNF QRP because they reflect the two dimensions of function separately, and believe these measures more accurately capture each functional domain over the proposed DC Function measure. One commenter noted that separate measures would allow for better understanding of the optimal interventions and outcomes for residents in each unique PAC setting. One of these commenters additionally asked CMS to introduce two separate DC Function measures for both mobility and self-care.

Response: The DC Function measure is intended to summarize several cross-setting functional assessment items while meeting the requirements of section 1899B(c)(1) of the Act. We agree with the commenters that the individual Discharge Self-Care Score and Discharge Mobility Score measures will continue to be useful to assess care quality in these dimensions. For this reason, the Discharge Self-Care Score and Discharge Mobility Score measures, which include additional self-care and mobility items, are not proposed for removal. SNFs will be able to use information from both the DC Function measure and these ''individual function measures'' (Discharge Self-Care Score and Discharge Mobility Score measures) when determining which functional areas may be opportunities for improvement, and for this reason, these two measures are not proposed for removal. We routinely reevaluate measures and will consider re-specifying the Discharge Self-Care Score and Discharge Mobility Score measures such that they more closely align with this proposed DC Function measure (for example, using statistical imputation).

Comment: Two commenters disagreed with characterizing items coded with an ANA code (codes 07, 09, 10, and 88) as ''missing'' data because these ANA codes represent clinical information. Thus, imputing scores for ANA codes would be clinically inappropriate. One of these commenters stated that imputation of these ANA codes based on other function activities would not improve the precision of the score.

Response: We would like to clarify that the use of the term ''missing'' data refers to codes that are not coded 01, 02, 03, 04, 05, or 06, which represent the amount of (or lack of) helper assistance a resident needed to complete a functional activity. ANA codes are considered ''missing'' in the context of the measure calculations since the observed discharge score is the sum of

[105] Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

01–06 values from functional assessment items included in the observed discharge score. Regarding the comment stating that imputation of these ANA codes based on other functional activities would not improve the precision of the score, we interpret the commenters to be saying that statistical imputation would not improve the precision of the score of missing item values. However, we disagree that using statistical imputation would not improve the precision of this value. Measure testing showed that the statistical imputation models demonstrate good discrimination and produce more precise and accurate estimates of function scores for items with missing scores when compared to the current imputation approach implemented in SNF QRP functional outcome measures, which recodes all ANAs as most dependent.

Comment: One commenter expressed concern that the proposed measure numerator is not wholly attributed to a SNF's quality of care and that the calculation of the ''expected'' discharge score is opaque, resulting in difficulty for SNFs to determine the score for which they are striving. This commenter further noted that functional goals are not based on statistical regression and are identified via individual-specific goals related to function, independence, and overall health.

Response: We agree with the commenter that functional goals are identified for each resident as a result of an individual assessment and clinical decisions, rather than statistics. We want to remind commenters that the DC Function measure is not calculated using the goals identified through the clinical process. The ''expected'' discharge score is calculated by risk-adjusting the observed discharge score (that is, the sum of individual function item values at discharge) for admission functional status, age, and clinical characteristics using an ordinary least squares linear regression model. The model intercept and risk-adjustor coefficients are determined by running the risk-adjustment model on all eligible SNF stays. For more detailed measure specifications, we direct readers to the document titled *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report.*[106] The risk-adjustment model for this measure controls for clinical, demographic, and function characteristics to ensure that the score fully reflects a facility's quality of care.

Comment: Three commenters encouraged CMS to provide SNFs a resource to calculate the expected discharge function score in real time, such that SNFs can implement these scores in care planning and monitoring efforts of residents prior to receiving confidential feedback reports. One of these commenters noted that such resources are necessary as calculations of the expected scores are complex and beyond easy comprehension for SNFs. Another commenter encouraged CMS to work with interested parties to develop the tools and educational resources necessary for SNFs to be able to obtain the individual resident's risk-adjusted predicted discharge function score when the assessments are completed. One commenter specifically requested that this information be included in the SNF's Review and Correct reports found in the internet Quality Improvement and Evaluation System (iQIES). Additionally, guidance should be developed and disseminated on how to use that information as a resource to inform and monitor the plan of care, so that necessary reassessments and modifications can be made in a timely manner in the event progress toward the predicted discharge function outcomes appear not to be satisfactory.

Response: We do not expect SNFs to replicate the methodology used to calculate this measure; however, the resources necessary to carry out such calculations will be available in the technical specifications posted on the SNF QRP Measures and Technical Specification website. Additionally, while the measure relies on statistical imputation to impute missing values, the steps used to calculate expected scores based on a given set of assessment items and their values are exactly the same as the Discharge Self-Care Score, Change in Self-Care Score, Discharge Mobility Score, and Change in Mobility Score already adopted in the SNF QRP. Given this, the concept of the expected score is no more complex than the functional outcome measures that have been in use for several years.

With respect to the comment regarding access to expected scores, we want to clarify that expected scores are not intended to be used for care planning; rather, care planning should be based on clinical judgement, assessment of residents' clinical status (including functional abilities and/or deficits), and residents' functional goals. Additionally, we have concerns that providing expected scores in such a real-time manner prior to the end of the data submission period may incentivize some SNFs to modify their scores and/or otherwise influence their coding practices. Given that SNFs have been able to use the current functional outcome measures to improve their care processes without the expected function scores, we maintain that SNFs will be able to similarly do so for the DC Function measure. However, we do appreciate that understanding how individuals' observed scores compared to expected scores can potentially allow SNFs to identify areas for improvement and will consider adding resident-level expected scores to the confidential feedback reports as technically feasible.

Comment: Three commenters expressed concern regarding the validity of reported functional assessment data. Two commenters oppose the adoption of the DC Function measure, stating that provider-reported functional assessment information is not accurate and incomplete, so when measures are calculated, scores are incorrect. With this in mind, two of these commenters recommended CMS improve SNFs' reporting of functional assessment data before adopting this measure. One of these commenters noted that some SNFs code resident function in response to payment incentives and noted that differential coding practices and profitability by case type across SNFs may contribute to differential profitability. Additionally, this commenter stated that the current imputation approach (which recodes all ANAs to 1) would lead to a lower motor score and raise Medicare payment for the stay and supported the proposal to improve the quality of the MDS data by using statistical imputation.

Response: We are aware of the concerns and challenges related to provider-reported data and acknowledge that the coding of GG items may be affected by payment and quality reporting considerations. We actively monitor SNF (and other PAC) coding practices to identify potential threats to the validity, and these analyses ultimately resulted in our development of the proposed DC Function measure. By using all available relevant information to impute ANAs, rather than simply imputing the most dependent value of 1, the statistical imputation approach mitigates payment-related incentives to code ANAs, while improving validity, as demonstrated through the measure's testing results. We acknowledge the importance of utilizing valid assessment data, and we remind commenters that we will be implementing a validation process for MDS-based measures starting in the same FY as the performance period of the measure. We

[106] Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

believe that adopting this validation process in parallel with the adoption of the measure will increase the accuracy of the data reported.

With respect to the comment about coding resident function in response to payment incentives, we have processes in place to ensure reported patient data are accurate. The MDS process has multiple regulatory requirements. Our regulations at §§ 483.20(b)(1)(xviii),(g), and (h) require that (1) the assessment must be a comprehensive, accurate assessment of the resident's status, (2) the assessment must accurately reflect the resident's status, (3) a registered nurse and each individual who completes a portion of the assessment must sign and certify the assessment is completed, and (4) the assessment process must include direct observation, as well as communication with the resident.[107]

Comment: Four commenters oppose the adoption of the DC Function measure due to the belief that this measure encourages SNFs to favor residents with the potential for improvement at discharge over those in need of maintenance care. For this reason, three of these commenters believe there needs to be an additional measure reflecting maintenance care and services; otherwise, incorporation of the DC Function measure in the QRP would incentivize SNFs to forgo provision of maintenance services to Medicare beneficiaries.

Response: The DC Function measure does not solely reflect improvement of residents at discharge. The measure estimates the percentage of residents who meet, as well as exceed, an expected discharge function score. In other words, if a resident, based on their own demographic and clinical characteristics, is expected to maintain, as opposed to improve in, function, then they will still meet the numerator criteria for this measure. For many residents, the overall goals of SNF care may include optimizing functional improvement, returning to a previous level of independence, maintaining functional abilities, or avoiding institutionalization. For additional details regarding risk adjustment, please refer to the *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report.*[108]

Comment: One commenter requested CMS provide more clarity on its imputation approach to recoding, specifically contrasting it with a Rasch analysis used in the unified PAC PPS prototype, to ensure transparency and clinical meaningfulness.

Response: The Rasch analysis in the unified PAC PPS prototype produces a single value to which every single ANA is recoded for a given item across all residents and settings. By contrast, under the imputation approach for the DC Function measure, we estimate a different imputed value for each resident, based on their clinical comorbidities, their score on all other GG items, and setting. We believe our approach accounts for several likely effects: setting-specific coding guidance and practice differences; function scores being correlated with clinical comorbidities; and functional scores for a given GG item being correlated with functional codes on other GG items, particularly on ''adjacent'' (similar) items. Therefore, we believe recoding ANAs based on each resident's specific clinical risk and using all available GG item scores/codes is a more valid approach. For more detailed measure specifications, we direct readers to the document titled *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report.*[109]

Comment: Two commenters oppose the adoption of the DC Function measure due to potential negative effects arising from Medicare Advantage (MA) plans focusing on money-saving practices. One commenter stated that if discharge measures only examine a discharge functional score in SNFs rather than a change in functional score in SNF and other PAC settings, MA plans can circumvent measurements of quality by sending difficult rehabilitation candidates to home rehabilitation, even if SNF or IRF rehabilitation would be better for the resident.

Response: We do not understand the connections raised by the commenter between the adoption of the DC Function measure and unintended consequences MA beneficiaries could face. However, if the concern stems from a belief that the DC Function measure would only be adopted in the SNF setting, we would like to clarify that aligned versions of the DC Function measure are also proposed for the IRF, LTCH, and HH QRPs.

Additionally, the Change in Mobility Score and Change in Self-Care Score measures rely on functional status items not yet collected in all settings and utilize a set of items that are not equally applicable across all settings. On the other hand, the DC Function score measure is a cross-setting measure that utilizes a standardized set of self-care and mobility assessment items that are common to all the PAC settings and are aligned in terms of the exclusions and risk models applied (as appropriate and feasible).

Comment: One commenter expressed concern that the measure performance may not adequately demonstrate functional ability improvements across the mobility and selfcare domains during the SNF stay. This commenter noted that the measure only includes a subset of function items from the assessment instrument and is concerned that these items are not necessarily the best indicators of resident functional success when discharged; for example, functional abilities and goals that better reflect self-care included upper body dressing and lower body dressing. This commenter also stated that the functional items captured in this measure seem to be based solely on ensuring cross-setting applicability and less on the accuracy of an expected function score.

Response: We acknowledge that the cross-setting applicability was a motivating factor in determining function items captured in the proposed DC Function measure, and upper body dressing and lower body dressing function items were not available across settings. Nonetheless, the proposed DC Function measure does reflect the progress of a resident across both the mobility and selfcare domains. As stated in section VII.C.1.b.3. of this final rule, the TEP supported the inclusion of both functional domains as self-care items impact mobility items and are clinically relevant to function. Additionally, the proposed measure is meant to supplement, rather than replace, the Discharge Self-Care Score and Discharge Mobility Score measures which implement the remaining self-care and mobility function items not captured in the DC Function measure. High correlations between the proposed measure and the Discharge Self-Care Score and Discharge Mobility Score measures (0.85 and 0.88, respectively) demonstrate that these three measures capture related, but distinct, aspects of provider care in relation to residents' function. The TEP understood these considerations and supported the inclusion of the function items included in the proposed measure.

Comment: One commenter believed that the adoption of the proposed measure would result in additional burden, stating that its adoption will

[107] 42 CFR 483.20.

[108] Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

[109] Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report. *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

require software updates to implement and monitor the measure's complex calculations prior to CMS publishing results, as well as additional training and education for clinical and administrative personnel. Another commenter noted that to achieve high measure scores, SNFs would require continuing education, time to perform and report assessments, and increased collaboration among clinicians.

Response: We disagree that the adoption of the proposed measure would result in additional burden or require additional training. We are not proposing changes to the number of items required or the reporting frequency of the items reported in the MDS in order to report for this measure. In fact, this measure requires the same set of items that are already reported by SNFs in the MDS. Additionally, we calculate this measure, and provide SNFs with various resources to review and monitor their own performance on this measure, including provider preview reports. Therefore, SNFs are not required to update software to successfully report or monitor performance. Regarding the commenter's concerns about education, we do plan to provide educational resources to SNFs about the DC Function measure.

Comment: Two commenters raised concerns that the measure does not account for cognition and communication. One commenter urged CMS to consider alternative assessments that better incorporate cognition and communication into the measure calculation. The other commenter similarly raised concerns that section GG items insufficiently capture all elements of function and do not adequately capture the outcomes required for safety and independence.

Response: We agree that cognition and communication are critically important and related to the safety and independence of residents. Although not directly assessed for the purpose of measure calculation, this measure does indirectly capture a facility's ability to impact a resident's cognition and communication to the extent that these factors are correlated to improvements in self-care and mobility. That said, we agree that communication and cognition are important to assess directly, and facilities currently do so through completion of the Brief Interview for Mental Status (BIMS), Confusion Assessment Method (CAM©), and Speech/Communication items in section B of the MDS. Additionally, we regularly assess the measures in the SNF QRP for measurement gaps, and as described in section VII.D. of this final rule, specifically identified cognitive improvement as a possible measurement gap and sought feedback about how to best assess this clinical dimension. We will use feedback from this RFI, as well as discussion with technical experts and empirical analyses to determine how to measure communication and cognition.

Comment: One commenter urged CMS to monitor the impact of COVID–19 and social determinants of health on functional outcomes and address these impacts in measure refinements.

Response: We recognize that COVID–19 and social determinants of health may have an impact on functional outcomes. Testing indicates that adding social determinants of health, such as dual eligibility and race/ethnicity, does not substantively affect provider scores for this measure. However, we will continue to monitor the impact of the above factors, as is feasible, on the measures and incorporate them in measure calculations, as needed, to ensure the measure remains valid and reliable.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the DC Function measure as an assessment-based outcome measure beginning with the FY 2025 SNF QRP as proposed.

c. Removal of the Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function Beginning With the FY 2025 SNF QRP

We proposed to remove the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan) measure from the SNF QRP beginning with the FY 2025 SNF QRP. Section 413.360(b)(2) of our regulations describes eight factors we consider for measure removal from the SNF QRP, and we believe this measure should be removed because it satisfies two of these factors.

First, the Application of Functional Assessment/Care Plan measure meets the conditions for measure removal factor one: measure performance among SNFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.[110] Second, this measure meets the conditions for measure removal factor six: there is an available measure that is more strongly associated with desired resident functional outcomes. We believe the proposed DC Function measure discussed in the FY 2024 SNF PPS proposed rule (88 FR 21337 through 21342) better measures functional outcomes than the current Application of Functional Assessment/Care Plan measure. We discuss each of these reasons in more detail.

In regard to measure removal factor one, the Application of Functional Assessment/Care Plan measure has become topped out,[111] with average performance rates reaching nearly 100 percent over the past 3 years (ranging from 99.1 percent to 98.9 percent during CYs 2019 through 2021).[112] [113] [114] For the 12-month period of Q3 2020 through Q2 2021 (July 1, 2020 through June 30, 2021), SNFs had an average score for this measure of 98.8 percent, with nearly 70 percent of SNFs scoring 100 percent[115] and for CY 2021, SNFs had an average score of 98.9 percent, with nearly 63 percent of SNFs scoring 100 percent.[116] The proximity of these mean rates to the maximum score of 100 percent suggests a ceiling effect and a lack of variation that restricts distinction among SNFs.

In regard to measure removal factor six, the proposed DC Function measure is more strongly associated with desired resident functional outcomes than this current process measure, the Application of Functional Assessment/Care Plan measure. As described in the FY 2024 SNF PPS proposed rule (88 FR 21339 through 213340), the DC Function measure has the predictive ability to distinguish residents with low

[110] For more information on the factors CMS uses to base decisions for measure removal, we refer readers to the Code of Federal Regulations, § 413.360(b)(2). *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-413/subpart-J/section-413.360.*

[111] Centers for Medicare & Medicaid Services. 2022 Annual Call for Quality Measures Fact Sheet, p. 10. *https://www.cms.gov/files/document/mips-call-quality-measures-overview-fact-sheet-2022.pdf.*

[112] Centers for Medicare & Medicaid Services. Nursing Homes including Rehab Services Data Archive, 2020. Annual Files National Data 10–20. PQDC, *https://data.cms.gov/provider-data/archived-data/nursing-homes.*

[113] Centers for Medicare & Medicaid Services. Nursing Homes including Rehab Services Data Archive, 2022. Annual Files National Data 06–22. PQDC, *https://data.cms.gov/provider-data/archived-data/nursing-homes.*

[114] Centers for Medicare & Medicaid Services. Nursing Homes including Rehab Services Data Archive, 2022. Annual Files National Data 10–22. PQDC, *https://data.cms.gov/provider-data/archived-data/nursing-homes.*

[115] Centers for Medicare & Medicaid Services. Nursing Homes including Rehab Services Data Archive, 2022. Annual Files Provider Data 05–22. PQDC, *https://data.cms.gov/provider-data/archived-data/nursing-homes.*

[116] Centers for Medicare & Medicaid Services. Nursing Homes including Rehab Services Data Archive, 2022. Annual Files Provider Data 10–22. PQDC, *https://data.cms.gov/provider-data/archived-data/nursing-homes.*

expected functional capabilities from those with high expected functional capabilities.[117] We have been collecting standardized functional assessment elements across PAC settings since 2016, which has allowed for the development of the proposed DC Function measure and meets the requirements of the Act to submit standardized patient assessment data and other necessary data with respect to the domain of functional status, cognitive function, and changes in function and cognitive function. In light of this development, this process measure, the Application of Functional Assessment/Care Plan measure, which measures only whether a functional assessment is completed and a functional goal is included in the care plan, is no longer necessary, and can be replaced with a measure that evaluates the SNF's outcome of care on a resident's function.

Because the Application of Functional Assessment/Care Plan measure meets measure removal factors one and six, we proposed to remove it from the SNF QRP beginning with the FY 2025 SNF QRP. We also proposed in the FY 2024 SNF PPS proposed rule (88 FR 21361) that public reporting of the Application of Functional Assessment/Care Plan measure would end by the October 2024 Care Compare refresh or as soon as technically feasible when public reporting of the proposed DC Function measure would begin.

Under our proposal, SNFs would no longer be required to report a Self-Care Discharge Goal (that is, GG0130, Column 2) or a Mobility Discharge Goal (that is, GG0170, Column 2) beginning with residents admitted on or after October 1, 2023. We would remove the items for Self-Care Discharge Goal (that is, GG0130, Column 2) and Mobility Discharge Goal (that is, GG0170, Column 2) with the next release of the MDS. Additionally, these items would not be required to meet SNF QRP requirements beginning with the FY 2025 SNF QRP.

We solicited public comment on our proposal to remove the Application of Functional Assessment/Care Plan measure from the SNF QRP beginning with the FY 2025 SNF QRP. The following is a summary of the comments we received on our proposal to remove the Application of Functional Assessment/Care Plan measure from the SNF QRP beginning with the FY 2025 SNF QRP and our responses.

Comment: Several commenters expressed support for the removal of the Application of Functional Assessment/Care Plan measure. Some of the commenters agreed with the removal of the measure because of the measure's topped out performance and due to the costs associated with tracking duplicate measures. A few of these commenters believe the DC Function measure better reflects the care delivered during a SNF stay.

Response: We thank the commenters for their support and agree that the Application of Functional Assessment/Care Plan measure should be removed due to topped-out performance. Additionally, we agree with the commenters that the DC Function measure better reflects care delivered in SNFs.

After consideration of the public comments we received, we are finalizing our proposal to remove the Application of Functional Assessment/Care Plan measure from the SNF QRP beginning with the FY 2025 SNF QRP as proposed.

d. Removal of the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients and Removal of the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients Beginning With the FY 2025 SNF QRP

We proposed to remove the Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Self-Care Score) and the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (Change in Mobility Score) measures from the SNF QRP beginning with the FY 2025 SNF QRP. Section 413.360(b)(2) of our regulations describe eight factors we consider for measure removal from the SNF QRP, and we proposed removal of this measure because it satisfies measure removal factor eight: the costs associated with a measure outweigh the benefits of its use in the program.

Measure costs are multifaceted and include costs associated with implementing and maintaining the measure. On this basis, we proposed to remove these measures for two reasons. First, the costs to SNFs associated with tracking similar or duplicative measures in the SNF QRP outweigh any benefit that might be associated with the measures. Second, our costs associated with program oversight of the measures, including measure maintenance and public display, outweigh the benefit of information obtained from the measures. We discuss each of these in more detail below.

We adopted the Change in Self-Care Score and Change in Mobility Score measures in the FY 2018 SNF PPS final rule (82 FR 36578 through 36593), under section 1888(e)(6)(B)(i)(II) of the Act because the measures meet the functional status, cognitive function, and changes in function and cognitive function domain under section 1899B(c)(1) of the Act. Two additional measures addressing the functional status, cognitive function, and changes in function and cognitive function domain were adopted in the same program year: the Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (Discharge Self-Care Score) and the Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (Discharge Mobility Score) measures. At the time these four outcome measures were adopted, the amount of rehabilitation services received among SNF residents varied. We believed that measuring residents' functional changes across all SNFs on an ongoing basis would permit identification of SNF characteristics associated with better or worse resident risk adjustment outcomes as well as help SNFs target their own quality improvement efforts.[118]

We proposed to remove the Change in Self-Care Score and Change in Mobility Score measures because we believe the SNF costs associated with tracking duplicative measures outweigh any benefit that might be associated with the measures. Since the adoption of these measures in 2018, we have been monitoring the data and found that the scores for the two self-care functional outcome measures, Change in Self-Care Score and Discharge Self-Care Score, are very highly correlated in SNF settings (0.93).[119] Similarly, in the monitoring data, we have found that the scores for the two mobility score measures, Change in Mobility Score and Discharge Mobility Score, are very highly

[117] ''Expected functional capabilities'' is defined as the predicted discharge function score.

[118] **Federal Register**. Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2018. *https://www.federalregister.gov/documents/2017/05/04/2017-08521/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities#p-397*.

[119] Acumen, LLC and Abt Associates. Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures, July 14–15, 2021: Summary Report. February 2022. *https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf*.

correlated in SNF settings (0.95).[120] The high correlation between these measures suggests that the Change in Self-Care Score and Discharge Self-Care Score and the Change in Mobility Score and the Discharge Mobility Score measures provide almost identical information about this dimension of quality to SNFs and are therefore duplicative.

Our proposal to remove the Change in Self-Care Score and the Change in Mobility Score measures is supported by feedback received from the TEP convened for the Refinement of LTCH, IRF, SNF/NF, and HH Function Measures. As described in the FY 2024 SNF PPS proposed rule (88 FR 21340 through 21341), the TEP panelists were presented with analyses that demonstrated the ''Change in Score'' and ''Discharge Score'' measure sets are highly correlated and do not appear to measure unique concepts, and they subsequently articulated that it would be sensible to retire either the ''Change in Score'' or ''Discharge Score'' measure sets for both self-care and mobility. Based on responses to the post-TEP survey, the majority of panelists (nine out of 12 respondents) suggested that only one measure set each for self-care and mobility, respectively, is necessary. Of those nine respondents, six preferred retaining the ''Discharge Score'' measure set over the ''Change in Score'' measure set.[121]

Additionally, we proposed to remove the Change in Self-Care Score and Change in Mobility Score measures because the program oversight costs outweigh the benefit of information that CMS, SNFs, and the public obtain from the measures. We must engage in various activities when administering the QRPs, such as monitoring measure results, producing provider preview reports, and ensuring the accuracy of the publicly reported data. Because these measures essentially provide the same information to SNFs as well as to consumers as the Discharge Self-Care Score and Discharge Mobility Score measures, our costs associated with measure maintenance and public display outweigh the benefit of information obtained from the measures.

Because these measures meet the criteria for measure removal factor eight, we proposed to remove the Change in Self-Care Score and Change in Mobility Score measures from the SNF QRP beginning with the FY 2025 SNF QRP. We also proposed that public reporting of the Change in Self-Care Score and the Change in Mobility Score measures would end by the October 2024 Care Compare refresh or as soon as technically feasible.

We solicited public comment on our proposal to remove the Change in Self-Care Score and the Change in Mobility Score measures from the SNF QRP beginning with the FY 2025 SNF QRP. The following is a summary of the comments we received on our proposal to remove the Change in Self-Care Score and the Change in Mobility Score measures from the SNF QRP beginning with the FY 2025 SNF QRP and our responses.

Comment: Several commenters expressed their support for the removal of the Change in Self-Care Score and the Change in Mobility Score measures, noting that these measures are duplicative of other measures and that their removal will reduce costs to SNFs and to CMS.

Response: We thank the commenters for their support on the removal of the Change in Self-Care Score and the Change in Mobility Score measures. We agree that the measures are duplicative and that their removal will reduce costs to SNFs and CMS.

Comment: Several commenters did not agree with the removal of the Change in Self-Care Score and Change in Mobility Score measures because they believe these measures provide more information than the Discharge Self-Care Score and the Discharge Mobility Score measures. Specifically, two of these commenters contended that capturing the amount of change in a resident's experience is more valuable than capturing whether residents meet or exceed an expected discharge score during their stay. One commenter advised CMS to keep the Change in Self-Care Score and Change in Mobility Score measures in the SNF QRP because the new DC Function measure lacks the positive characteristics the Change in Self-Care Score and Change in Mobility Score measures capture. Meanwhile, another commenter encouraged CMS to consider how it can incorporate the positive aspects of these measures into the new DC Function measure.

Response: We appreciate the perspective of the commenters and understand that there are advantages and disadvantages to retiring the Change in Self-Care Score and Change in Mobility Score measures rather than the Discharge Self-Care Score and Discharge Mobility Score measures. We weighed the tradeoffs of these measures in consultation with a TEP, comprised of 15 panelists with diverse perspectives and areas of expertise, including SNF representation.[122] The majority of the TEP favored the retirement of the Change in Self-Care Score and Change in Mobility Score measures because they believed the Discharge Self-Care Score and Discharge Mobility Score measures better capture a resident's relevant functional ability. We agree that it is important for facilities to track the amount of change that occurs over the course of a stay for its residents and would like to point out that the removal of the Change in Self-Care Score and Change in Mobility Score measures does not preclude SNFs' abilities in this regard. However, we also believe that the Change in Self-Care Score and Change in Mobility Score measures are not intuitive to interpret for the primary audience of Care Compare, as the units of change and what constitutes a meaningful change are unfamiliar to the vast majority of users, particularly prospective or current residents and their caregivers. This is in contrast to the Discharge Self-Care Score and Discharge Mobility Score measures, which are presented as simple proportions. Additionally, the correlations between the Change in Self-Care Score and Discharge Self-Care Score measures and Change in Mobility Score and Discharge Mobility Score measures are very high (Spearman correlation: 0.93 and 0.95), indicating the measures capture almost identical concepts and lead to very similar rankings.[123] As such, the testing does not support the claim that the Change in Self-Care Score and Change in Mobility Score measures provide significantly

[120] Acumen, LLC and Abt Associates. Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures, July 14–15, 2021: Summary Report. February 2022. *https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

[121] Acumen, LLC and Abt Associates. Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures, July 14–15, 2021: Summary Report. February 2022. *https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

[122] Acumen, LLC and Abt Associates. Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures, July 14–15, 2021: Summary Report. February 2022. *https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

[123] Acumen, LLC and Abt Associates. Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures, July 14–15, 2021: Summary Report. February 2022. *https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

more information on which to compare facilities, as the relative rankings of facilities are very similar between the Change in Self-Care Score and Discharge Self-Care Score measures and the Change in Mobility Score and Discharge Mobility Score measures. Consequently, given the TEP's recommendation, the more intuitive interpretation, and the very high correlations, we believe there is more value in retiring the Change in Self-Care Score and Change in Mobility Score measures and retaining the Discharge Self-Care Score and Discharge Mobility Score measures.

Comment: One commenter raised concerns that the methodology used to calculate the Discharge Self-Care Score and Discharge Mobility Score measures does not account for functional abilities at admission in the way that the Change in Self-Care Score and Change in Mobility Score measures being proposed for removal do. The commenter requested that CMS clarify the extent to which the remaining Discharge Self-Care Score and Discharge Mobility Score measures would account for change in a residents' function over time, as well as resident heterogeneity. These commenters also raised concerns about unintended consequences that could be introduced through the removal of the Change in Self-Care Score and Change in Mobility Score measures, such as the cherry-picking of residents or creating limited access to services for those with lower functional status. One of these commenters urged CMS to carefully evaluate whether the removal of the Change in Self-Care Score and Change in Mobility Score measures could lead to such unintended consequences.

Response: We appreciate that measures of functional outcomes must account for resident case-mix to ensure fair and meaningful comparisons across facilities. Accordingly, the Discharge Self-Care Score and Discharge Mobility Score measures that would remain in the SNF QRP do in fact account for functional abilities at admission, as well as other relevant demographic and clinical characteristics (*see, for example, Skilled Nursing Facility Quality Reporting Program Measure Calculations and Reporting User's Manual Version 4.0.*).[124] Specifically, the expected discharge scores, which residents must meet or exceed to meet the Discharge Self-Care Score and Discharge Mobility Score measures' numerators, are predicted using the residents' observed admission function scores plus the same clinical comorbidities and demographic characteristics as the corresponding Change in Self-Care Score and Change in Mobility Score measures. Given that the Discharge Self-Care Score and Discharge Mobility Score measures do account for functional abilities at admission, among other relevant clinical characteristics that can impact functional improvement, we do not anticipate that the removal of the Change in Self-Care Score and Change in Mobility Score measures will increase any incentive to cherry -pick residents or block access to care. We take the appropriate access to care in SNFs very seriously, and routinely monitor the performance of measures in the SNF QRP, including performance gaps across SNFs. We will continue to monitor closely whether any proposed changes to the SNF QRP have unintended consequences on access to care for high-risk residents. Should we find any unintended consequences, we will take appropriate steps to address these issues in future rulemaking.

Comment: A few commenters recommended the removal of the Discharge Self-Care Score and Discharge Mobility Score measures instead, which they believe are duplicative of the proposed DC Function Measure.

Response: We disagree that the currently adopted Discharge Self-Care Score and Discharge Mobility Score measures are duplicative of the proposed DC Function measure. As discussed in section VII.C.1.b.1.a. of the final rule, the Discharge Self-Care Score and Discharge Mobility Score measures are not cross-setting because they rely on functional status items not collected in all PAC settings and thus do not satisfy requirement of a cross-setting quality measure as set forth in sections 1888(e)(6)(B)(i)(II) and 1899B(c)(1)(A) of the Act. In contrast, the DC Function measure does include functional status items collected in each of the four PAC settings. Moreover, the DC Function measure captures information that is distinct from the Discharge Self-Care and Discharge Mobility Score measures. Specifically, the DC Function measure considers both dimensions of function within a single measure (utilizing a subset of self-care and mobility GG items in the MDS), while the Discharge Self-Care Score and Discharge Mobility score measures each consider one dimension of function (utilizing all self-care and mobility GG items, respectively).

After consideration of the public comments we received, we are finalizing our proposal to remove the Change in Self-Care Score and Change in Mobility Score measures from the SNF QRP beginning with the FY 2025 SNF QRP as proposed.

2. SNF QRP Quality Measures Beginning With the FY 2026 SNF QRP

a. CoreQ: Short Stay Discharge Measure (CBE #2614) Beginning With the FY 2026 SNF QRP

(1) Background

We define person-centered care as integrated healthcare services delivered in a setting and manner that is responsive to the individual and their goals, values and preferences, in a system that empowers residents and providers to make effective care plans together.[125] Person-centered care is achieved when healthcare providers work collaboratively with individuals to do what is best for the health and well-being of individuals receiving healthcare services, and allows individuals to make informed decisions about their treatment that align with their preferences and values, such as including more choice in medication times, dining options, and sleeping times. Self-reported measures, including questionnaires assessing the individual's experience and satisfaction in receiving healthcare services, are widely used across various types of providers to assess the effectiveness of their person-centered care practices.

There is currently no national standardized satisfaction questionnaire that measures a resident's satisfaction with the quality of care received by SNFs. We identified resident satisfaction with the quality of care received by SNFs as a measurement gap in the SNF QRP (see section VII.D. of this final rule), as did the MAP in its report *MAP* 2018 *Considerations for Implementing Measure in Federal Programs: Post-Acute Care and Long-Term Care.*[126] Currently the SNF QRP includes measures of processes and outcomes that illustrate whether interventions are working to improve delivery of healthcare services. However, we believe that measuring resident satisfaction would provide clinical teams compelling information to use when examining the results of their clinical care, and can help SNFs identify deficiencies that other quality

[124] Skilled Nursing Facility Quality Reporting Program Measure Calculations and Reporting User's Manual Version 4.0. October 2022. *https://www.cms.gov/files/document/snf-quality-measure-calculations-and-reporting-users-manual-v40.pdf.*

[125] Centers for Medicare & Medicaid Services. Innovation Center. Person-Centered Care. *https://innovation.cms.gov/key-concepts/person-centered-care.*

[126] National Quality Forum. MAP 2018 Considerations for Implementing Measures in Federal Programs—PAC–LTC. *https://www.qualityforum.org/Publications/2018/02/MAP_2018_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

metrics may struggle to identify, such as communication between a resident and the provider.

Measuring individuals' satisfaction with healthcare services using questionnaires has been shown to be a valid indicator for measuring person-centered care practices. The value of measuring consumer satisfaction is supported in the peer-reviewed literature using respondents from SNFs. One study demonstrated higher (that is, better) resident satisfaction is associated with the SNF receiving fewer deficiency citations from regulatory inspections of the SNF, and is also associated with higher perceived service quality.[127] Other studies of the relationship between resident satisfaction and clinical outcomes suggest that higher overall satisfaction may contribute to lower 30-day readmission rates [128] [129] [130] and better adherence to treatment recommendations.[131] [132]

We currently collect resident satisfaction data in other settings, such as home health, hospice, and hospital, using Consumer Assessment of Healthcare Providers and Systems (CAHPS®) patient experience surveys.[133] These CAHPS® surveys ask individuals (or in some cases their families) about their experiences with, and ratings of, their healthcare providers, and then we publicly report the results of some of these resident experience surveys on Care Compare.[134] The CAHPS® Nursing Home survey: Discharged Resident Instrument (NHCAHPS–D) was developed specifically for short-stay SNF residents [135] by the Agency for Healthcare Research and Quality (AHRQ) and the CAHPS® consortium [136] in collaboration with CMS. However, due to its length and the potential burden on SNFs and residents to complete it, we have not adopted it for the SNF QRP.

The CoreQ is another suite of questionnaires developed by a team of nursing home providers and researchers [137] to assess satisfaction among residents and their families. The CoreQ suite of five measures is used to capture resident and family data for SNFs and assisted living (AL) facilities. The CoreQ was developed in 2012 by SNFs and ALs that partnered with researchers to develop a valid resident satisfaction survey for SNFs and ALs since, at the time, there was no standard questionnaire or set of identical questions that could be used to compare meaningful differences in quality between SNFs. As part of the development of the CoreQ measures, extensive psychometric testing was conducted to further refine the CoreQ measures into a parsimonious set of questions that capture the domain of resident and family satisfaction. Since 2017, the CoreQ has been used in the American Health Care Association (AHCA) professional recognition program, and several States (including New Jersey, Tennessee, and Georgia) have incorporated the CoreQ into their Medicaid quality incentive programs. In addition, 42 SNF and AL customer satisfaction vendors currently administer the CoreQ measures' surveys or have added the CoreQ questions to their questionnaires.

The CoreQ measures were designed to be different from other resident satisfaction surveys. The primary difference between the CoreQ questionnaires for residents discharged from a SNF after receiving short-stay services and the NHCAHPS–D survey is its length: the CoreQ questionnaire consists of four questions while the NHCAHPS–D has 50 questions. Another difference is that the CoreQ measures provide one score that reflects a resident's overall satisfaction, while other satisfaction surveys do not. The CoreQ questionnaires use a 5-point Likert scale, and the number of respondents with an average score greater than or equal to 3.0 across the four questions is divided by the total number of valid responses to yield the SNF's satisfaction score.[138]

The CoreQ measures are also instruments that are familiar to the SNF community, and the CoreQ: Short Stay Discharge (CoreQ: SS DC) survey has already been voluntarily adopted by a large number of SNFs with ease. The number of SNFs voluntarily using the CoreQ: SS DC survey increased from 372 in the first quarter of 2016 to over 1,500 in the third quarter of 2019.[139] Additionally, the measure steward, AHCA, reported that there have been no reported difficulties with the current implementation of the measure, and in fact, providers, vendors, and residents have reported they like the fact that the questionnaire is short and residents report appreciation that their satisfaction (or lack thereof) is being measured.

(a) Measure Importance

Measuring residents' satisfaction is an effective method to assess whether the goals of person-centered care are achieved. Measuring residents' satisfaction can help SNFs identify deficiencies that the other quality metrics adopted in the SNF QRP cannot identify, such as communication between a resident and the SNF's healthcare providers. We believe collecting and assessing satisfaction data from SNF residents is important for understanding residents' experiences and preferences, while the collection process ensures each resident can easily and discreetly share their information in a manner that may help other potential consumers choose a SNF. Collection of resident satisfaction data also aligns with the person-centered care domain of CMS's Meaningful Measures 2.0

[127] Li Y, Li Q, Tang Y. Associations between Family Ratings on Satisfaction with Care and Clinical Quality-of-Care Measures for Nursing Home Residents. Med Care Res Rev. 2016 Feb;73(1):62–84. doi: 10.1177/1077558715596470. Epub 2015 Jul 21. PMID: 26199288; PMCID: PMC4712136.

[128] Boulding W, Glickman SW, Manary MP, Schulman KA, Staelin R. Relationship between Patient Satisfaction with Inpatient Care and Hospital Readmission within 30 days. Am J Manag Care. 2011 Jan;17(1):41–8. PMID: 21348567.

[129] Carter J, Ward C, Wexler D, Donelan K. The Association between Patient Experience Factors and Likelihood of 30-day Readmission: a Prospective Cohort Study. *BMJ* Qual Saf. 2018;27:683–690. doi: 10.1136/bmjqs–2017–007184. PMID: 29146680.

[130] Anderson PM, Krallman R, Montgomery D, Kline-Rogers E, Bumpus SM. The Relationship Between Patient Satisfaction With Hospitalization and Outcomes Up to 6 Months Post-Discharge in Cardiac Patients. J Patient Exp. 2020;7(6):1685–1692. doi: 10.11771237437352094838 9. PMID: 33457631 PMCID: PMC7786784.

[131] Barbosa CD, Balp MM, Kulich K, Germain N, Rofail D. A Literature Review to Explore the Link Between Treatment Satisfaction and Adherence, Compliance, and Persistence. Patient Prefer Adherence. 2012;6:39–48. doi: 10.2147/PPA.S24752. Epub 2012 Jan 13. PMID: 22272068; PMCID: PMC3262489.

[132] Krot K, Rudawska I. Is Patient Satisfaction the Key to Promote Compliance in Health Care Sector? Econ Sociol. 2019;*12(3)*:291–300. doi: 10.14254/2071–789X.2019/12–3/19.

[133] Centers for Medicare & Medicaid Services. Consumer Assessment of Healthcare Providers & Systems (CAHPS). *https://cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS.*

[134] Care Compare. *https://www.medicare.gov/care-compare/.*

[135] Sangl J, Bernard S, Buchanan J, Keller S, Mitchell N, Castle NG, Cosenza C, Brown J, Sekscenski E, Larwood D. The development of a CAHPS instrument for nursing home residents. J Aging Soc Policy. 2007;19(2):63–82. doi: 10.1300/J031v19n02_04. PMID: 17409047.

[136] The CAHPS consortium included Harvard Medical School, The RAND Corporation, and Research Triangle Institute International.

[137] The CoreQ was developed by Nicholas Castle, Ph.D., the American Health Care Association/National Center for Assisted Living (AHCA/NCAL), and providers with input from customer satisfaction vendors and residents.

[138] What is CoreQ? *www.coreq.org.*

[139] CoreQ_Short_Stay_Appendix_Final_updated_Jan2020_Corrected_April2020_FinalforSubmission-637229961612228954.docx. Available in the measure's specifications from the Patient Experience and Function Spring Cycle 2020 project. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/36/Spring/2020/measures/2614/shared/2614.zip.*

Framework,[140] and would provide SNFs with resident-reported outcome information to incorporate into their quality assessment and performance improvement (QAPI) strategies to improve their quality of care.

The CoreQ: SS DC measure is a resident-reported outcome measure using the CoreQ: SS DC measure questionnaire which calculates the percentage of residents discharged in a 6-month period from a SNF, within 100 days of admission, who are satisfied with their SNF stay. The CoreQ: SS DC measure received initial CBE endorsement in 2016 and re-endorsement in 2020, and is a widely accepted instrument for measuring resident satisfaction. The measure includes a parsimonious set of four questions, and represents an important aspect of quality improvement and person-centered care. We believe it could be used to fill the identified gap in the SNF QRP's measure set, that is, measuring residents' experience of care. Therefore, we proposed to adopt the CoreQ: SS DC measure for the SNF QRP beginning with the FY 2026 SNF QRP. More information about the CoreQ questionnaire is available at *http://www.coreq.org.*

(b) Measure Testing

The measure steward, AHCA, conducted extensive testing on the CoreQ: SS DC measure to assess reliability and validity prior to its initial CBE endorsement in 2016 and conducted additional analyses for the CoreQ: SS DC measure's CBE re-endorsement in 2020. These analyses found the CoreQ: SS DC measure to be highly reliable, valid, and reportable.[141] We describe the results of these analyses in this section.

Reliability testing included administering a pilot survey to 853 residents, re-administering the survey to 100 of these residents, and then examining results at the data element level, the respondent/questionnaire level, and the measure (that is, facility) level. The data elements of the CoreQ: SS DC measure were found to be highly repeatable, with pilot and re-administered responses agreeing between 94 percent and 97 percent of the time, depending on the question. In other words, the same results were produced a high proportion of the time when assessed in the same population in the same time period. The questionnaire-level scores were also highly repeatable, with pilot and re-administered responses agreeing 98 percent of the time. Finally, reliability at the measure (that is, facility) level was also strong. Bootstrapping analyses in which repeated draws of residents were randomly selected from the measure population and scores were recalculated showed that 17.82 percent of scores were within 1 percentage point of the original score, 38.14 percent were within 3 percentage points of the original score, and 61.05 percent were within 5 percentage points of the original score. These results demonstrate that the CoreQ: SS DC measure scores from the same facility are very stable across bootstrapped samples.

The measure steward also conducted extensive validity testing of the CoreQ: SS DC measure's questionnaire, which included examination of the items in the questionnaire, the questionnaire format, and the validity of the CoreQ: SS DC measure itself.[142]

First, the measure steward tested the items in the CoreQ: SS DC questionnaire to determine if a subset of items could reliably be used to produce an overall indicator of customer satisfaction. The measure steward started with 22 pilot questions, which assessed an individual's satisfaction with a number of concepts, such as food, environment, activities, communication, and responsiveness. Through repeated analyses, the number of questions was narrowed down to four. The four questions in the CoreQ: SS DC measure's final questionnaire were found to have a high degree of criterion validity, supporting that the instrument measures a single concept of ''customer satisfaction,'' rather than multiple areas of satisfaction.

Next, the validity of the four-question CoreQ: SS DC measure summary score was compared to the more expansive set of 22 pilot questions, and was found to have a correlation value of 0.94, indicating that the CoreQ: SS DC measure's questionnaire consisting of four questions adequately represents the overall satisfaction of the facility.

Finally, the measure steward found moderate levels of construct validity and convergent validity when the CoreQ: SS DC measure's relationship with Certification and Survey Provider Enhanced Reports (CASPER) Quality Indicators, Nursing Home Compare Quality Indicators, Five Star Ratings and staffing levels was examined. Therefore, the CoreQ: SS DC measure's questionnaire format has a high degree of both face validity and content validity.[143]

Since the CoreQ: SS DC measure's original CBE endorsement in 2018, and its subsequent use by SNFs in quality improvement (see section VI.C.2.a.(1) of the proposed rule), the measure steward conducted additional testing, including examining the reportability of the measure. Testing found that when the CoreQ: SS DC measure's questionnaires were administered within one week of facility discharge, the response rate was 8 percent higher than if it was administered 2 weeks after facility discharge. The measure steward analyzed responses when it allowed up to 2 months for a resident to respond, and found the average time to respond to the CoreQ: SS DC questionnaire was 2 weeks, while the response rate dropped much lower in the second month after facility discharge.[144] The measure steward also conducted additional analyses to determine if there was any bias introduced into the responses to the CoreQ: SS DC's questionnaires that were returned during the second month, and found that average scores for the questionnaires returned in the second month were almost identical to those returned in the first month. Finally, the measure steward examined the time period required to collect the CoreQ: SS DC measure's data, and found that a majority of SNFs (that is, 90 percent) could achieve the minimum sample size of 20 completed CoreQ: SS DC questionnaires necessary for the satisfaction score to be reported as reliable for the SNF, when given up to 6 months. Additionally, once 125 consecutive completed CoreQ: SS DC questionnaires were received for a

[140] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[141] CoreQ_Short_Stay_Testing_Final_v7.1_Corrected_4_20_20_FinalforSubmission-637229958835088042.docx. Available in the measure's specifications from the Patient Experience and Function Spring Cycle 2020 project. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/36/Spring/2020/measures/2614/shared/2614.zip.*

[142] CoreQ_Short_Stay_Testing_Final_v7.1_Corrected_4_20_20_FinalforSubmission-637229958835088042.docx. Available in the measure's specifications from the Patient Experience and Function Spring Cycle 2020 project. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/36/Spring/2020/measures/2614/shared/2614.zip.*

[143] CoreQ_Short_Stay_Testing_Final_v7.1_Corrected_4_20_20_FinalforSubmission-637229958835088042.docx. Available in the measure's specifications from the Patient Experience and Function Spring Cycle 2020 project. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/36/Spring/2020/measures/2614/shared/2614.zip.*

[144] CoreQ Measure Worksheet-2614-Spring 2020 Cycle. Patient Experience and Function Project. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=93879.*

particular SNF, the measure steward found that including additional CoreQ: SS DC questionnaires had no additional effect on the SNF's satisfaction score. As a result of these additional analyses, the recommendations to allow up to 2 months for CoreQ: SS DC questionnaire returns, a 6-month reporting period, and a ceiling of 125 completed questionnaires in a 6-month period were incorporated into the CoreQ: SS DC measure's specification.

(2) Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act be endorsed by a CBE with a contract under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Although the CoreQ measure is CBE endorsed for SNFs, we did consider whether there were other CBE endorsed measures capturing SNF resident satisfaction after discharge from a SNF in less than 100 days. We found several CBE endorsed measures used in other programs that assess resident experiences for specific resident populations, such as residents at end of life, residents with low back pain, and residents receiving psychiatric care. However, we did not find other CBE endorsed measures that assess satisfaction of residents discharged within 100 days of their admission to the SNF.

(3) Interested Parties and Technical Expert Panel (TEP) Input

We employ a transparent process to seek input from interested parties and national experts and engage in a process that allows for pre-rulemaking input on each measure, under section 1890A of the Act. To meet this requirement, we solicited feedback from interested parties through an RFI in the FY 2022 SNF PPS proposed rule (86 FR 19998) on the importance, relevance, and applicability of patient-reported outcome (PRO) measures for SNFs. In the FY 2022 SNF PPS final rule (86 FR 42490 through 42491), we noted that several commenters supported the concept of PROs while others were uncertain what we intended with the term ''patient-reported outcomes.'' One commenter stressed the importance of PROs since they determine outcomes based on information obtained directly from residents, and therefore provide greater insight into residents' experience of the outcomes of care. Another commenter agreed and stated that residents and caregivers are the best sources of information reflecting the totality of the resident experience.

We solicited public comments from interested parties specifically on the inclusion of the CoreQ: SS DC measure in a future SNF QRP year through an RFI in the FY 2023 SNF PPS proposed rule (87 FR 22761 through 22762). In the FY 2023 SNF PPS final rule (87 FR 47555), we noted that support for the CoreQ: SS DC measure specifically was mixed among commenters. One commenter stated that since the CoreQ: SS DC measure has a limited number of questions, it may not fully reflect resident experience at a given facility. Another commenter would not support the CoreQ: SS DC measure since it excludes residents who leave a facility against medical advice and residents with guardians, and this commenter stated it would be important to hear from both of these resident populations. Two commenters cautioned us to consider the burden associated with contracting with third-party vendors to administer the CoreQ: SS DC measure.

(4) Measure Application Partnership (MAP) Review

The CoreQ: SS DC measure was initially endorsed by the CBE in 2016. It was originally reviewed by the CBE's Person- and Family-Centered Care (PFCC) Committee on June 6, 2016. The PFCC Committee members noted the importance of measuring residents' experiences and their preferences given health care's changing landscape. Overall, the PFCC Committee members liked that there was a conceptual framework associated with the measure submission that linked the CoreQ: SS DC measure with other improvement programs and organizational change initiatives that can help SNFs improve the quality of care they provide. Some PFCC Committee members expressed concern around the consistency of implementation across SNFs and whether scores could be compromised by a low response rate. All PFCC Committee members agreed to not risk-adjust the CoreQ: SS DC measure as it would be inappropriate to control for differences based on sociodemographic factors. We refer readers to the PFCC Final Report—Phase 3.[145]

The following year, the CoreQ: SS DC measure was included on the publicly available ''List of Measures under Consideration for December 1, 2017'' [146] for the SNF QRP Program, but the MAP did not receive any comments from interested parties. The CBE convened MAP PAC/LTC workgroup met on December 13, 2017 and provided input on the CoreQ: SS DC measure. The MAP PAC/LTC workgroup offered support of the CoreQ: SS DC measure for rulemaking, noting that it adds value by adding addressing a gap area for the SNF QRP. The MAP PAC/LTC workgroup emphasized the value of resident-reported outcomes and noted that the CoreQ: SS DC measure would reflect quality of care from the resident's perspective. However, the MAP PAC/LTC workgroup also noted the potential burden of collecting the data and cautioned that the implementation of a new data collection requirement should be done with the least possible burden to the SNF.[147]

(5) Quality Measure Calculation

The CoreQ: SS DC measure is a resident-reported outcome measure based on the CoreQ: SS DC questionnaire that calculates the percentage of residents discharged in a 6-month period from a SNF, within 100 days of admission, who are satisfied with their SNF stay. Unless otherwise exempt from collecting and reporting on the CoreQ: SS DC measure (as discussed in section VI.F.3.b. of the FY 2024 SNF PPS proposed rule), we proposed that each SNF must contract with an independent CMS-approved CoreQ survey vendor to administer the CoreQ: SS DC measure questionnaire, and report the results to us, on behalf of the SNF (as specified in sections VI.F.3.a. and VI.F.3.c. of the FY 2024 SNF PPS proposed rule).

The CoreQ: SS DC measure questionnaire utilizes four questions (hereafter referred to as the four primary questions) and uses a 5-point Likert scale as illustrated in Table C3.

[145] Person and Family Centered Care Final Report—Phase 3. *https://www.qualityforum.org/Publications/2017/01/Person_and_Family_Centered_Care_Final_Report_-_Phase_3.aspx.*

[146] Centers for Medicare & Medicaid Services. List of Measures under Consideration for December 1, 2017. *https://mmshub.cms.gov/sites/default/files/map-2017-2018-preliminary-recommendations.xlsx.*

[147] MAP Post-Acute Care/Long-Term Care Workgroup Project. 2017–2018 Preliminary Recommendations. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

TABLE 13—COREQ: SHORT STAY DISCHARGE PRIMARY QUESTIONS

Primary questions used in the CoreQ: short stay discharge questionnaire	Response options for the four CoreQ primary questions
1. In recommending this facility to your friends and family, how would you rate it overall? 2. Overall, how would you rate the staff? 3. How would you rate the care you received? 4. How would you rate how well your discharge needs were met?	Poor (1). Average (2). Good (3). Very Good (4). Excellent (5).

We also proposed to add two ''help provided'' questions to the end (as questions five and six) of the CoreQ: SS DC questionnaire to determine whether to count the CoreQ: SS DC questionnaire as a completed questionnaire for the CoreQ: SS DC measure denominator or whether the questionnaire should be excluded as described in the Draft CoreQ: SS DC Survey Protocols and Guidelines Manual [148] available on the SNF QRP Measures and Technical Information web page. These two ''help provided'' questions are:

5. Did someone help you [the resident] complete the survey?

6. How did that person help you [the resident]?

(a) Denominator

The denominator is the sum of all of the questionnaire-eligible residents, regardless of payer, who (1) are admitted to the SNF and discharged within 100 days, (2) receive the CoreQ: SS DC questionnaire, and (3) respond to the CoreQ: SS DC questionnaire within 2 months of discharge from the SNF. However, certain residents are excluded from the denominator and therefore are not sent a CoreQ: SS DC questionnaire by the CMS-approved CoreQ survey vendor or contacted by the CMS-approved CoreQ survey vendor for a phone interview. The residents who are not eligible to respond to the questionnaire, and therefore are excluded from the denominator for the CoreQ: SS DC measure are: (1) residents discharged to another hospital, another SNF, a psychiatric facility, an IRF, or an LTCH; (2) residents who die during their SNF stay; (3) residents with court-appointed legal guardians with authority to make decisions on behalf of the resident; (4) residents discharged to hospice; (5) residents who have dementia impairing their ability to answer the questionnaire; [149] (6) residents who left the SNF against medical advice; and (7) residents with a foreign address. Additionally, residents are excluded from the denominator if after the CoreQ: SS DC questionnaire is returned: (1) the CMS-approved CoreQ survey vendor received the CoreQ: SS DC completed questionnaire more than 2 months after the resident was discharged from the SNF or the resident did not respond to attempts to conduct the interview by phone within 2 months of their SNF discharge date; (2) the CoreQ: SS DC questionnaire ''help provided'' question six indicates the questionnaire answers were answered for the resident by an individual(s) other than the resident; or (3) the received CoreQ: SS DC questionnaire is missing more than one response to the four primary questions (that is, missing two or more responses).

(b) Numerator

The numerator is the sum of the resident respondents in the denominator that submitted an average satisfaction score of greater than or equal to 3 for the four primary questions on the CoreQ: SS DC questionnaire. If a CoreQ: SS DC questionnaire is received and is missing only one response (out of the four primary questions in the questionnaire), imputation is used which represents the average value from the other three available responses. If a CoreQ: SS DC questionnaire is received and is missing more than one response to the four primary questions (that is, missing two or more responses), the CoreQ: SS DC questionnaire is excluded from the analysis (that is, no imputation will be used for these residents). The CoreQ: SS DC measure is not risk-adjusted by sociodemographic status (SDS), as the measure steward found no statistically significant differences (at the 5 percent level) in scores between the SDS categories.[150] Additional information about how the CoreQ: SS DC measure is calculated is available in the Draft CoreQ: SS DC Survey Protocols and Guidelines Manual [151] on the SNF QRP Measures and Technical Information web page.

We solicited public comment on our proposal to adopt the CoreQ: SS DC Measure beginning with the FY 2026 SNF QRP. The following is a summary of the comments we received and our responses.

Comment: A number of commenters supported the adoption of the CoreQ: SS DC measure in the SNF QRP as a reliable and valid tool for assessing resident satisfaction. Several commenters noted the measure is CBE endorsed and expressed appreciation to CMS for proposing a measure that was supported by the MAP PAC/LTC workgroup for rulemaking. Two commenters pointed out that the CoreQ: SS DC survey is more efficient than other tools that have over 50 questions and provides a concise satisfaction rate that is intuitive for providers to act on and for consumers to understand. Another commenter supported the adoption of the CoreQ: SS DC measure not only because they believe it is an accurate measure of resident-centered care, but also because of its long tenure, validity testing, utilization in other settings, and cooperative development with SNFs and assisted living communities. One commenter noted the importance of residents/families providing direct feedback regarding the care and services received.

Response: We thank the commenters for their support of the CoreQ: SS DC measure. We agree that this CBE endorsed measure's survey is an efficient tool for both SNFs to implement and residents to complete, which would increase the likelihood

[148] Draft CoreQ: SS DC Survey Protocols and Guidelines Manual. Chapter VIII. Data Processing and Coding. Available on the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information.*

[149] Patients who have dementia impairment in their ability to answer the questionnaire are defined as having a BIMS score on the MDS 3.0 as 7 or lower. *https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=3436.*

[150] The measure developer examined the following SDS categories: age, race, gender, and highest level of education. CoreQ: Short Stay Discharge Measure.

[151] Draft CoreQ: SS DC Survey Protocols and Guidelines Manual. Chapter VIII. Data Processing and Coding. Available on the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information.*

that SNFs would receive robust responses they could use to advance their person-centered care practices. We agree that capturing residents' direct feedback is valuable and the proposed measure would fill a measurement gap in the SNF QRP.

We also received several comments that did not support our proposal to adopt the CoreQ: SS DC measure. Commenters gave various reasons including: a preference for using the NHCAHPS–D survey because it includes a greater number of questions; concern about the number of residents that would be excluded from receiving a CoreQ: SS DC survey; the imputation method used to calculate a CoreQ: SS DC measure score; and the burden of submitting resident information files to the CoreQ survey vendor on a weekly basis. The following is a summary of the comments we received and our responses.

Comment: While several commenters agreed that resident satisfaction surveys would provide clinical teams information to use when examining the results of their clinical care, and help SNFs identify areas for improvement, they did question why CMS did not choose to use the standardized measures contained in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) that were developed by CMS with the Agency for Healthcare Research and Quality (AHRQ), and specifically the CAHPS Nursing Home survey: Discharged Resident Instrument (NHCAHPS–D)—or a portion of this instrument. Two of these commenters cited the National Academies of Sciences, Engineering, and Medicine (NASEM) report, ''The National Imperative to Improve Nursing Home Quality,'' which recommended the use of the CAHPS survey, which was developed by the AHRQ, in conjunction with CMS.[152] Another commenter suggested that the use of surveys other than CAHPS conflicts with the CMS Foundational Measurement Strategy, which aims to align all adult and pediatric person-centered care domain measures with CAHPS surveys.

A number of these commenters also questioned why CMS would use a tool that was developed by the American Health Care Association (AHCA), which is the major nursing home trade association. These commenters pointed to the NASEM report's findings that many nursing homes promote and advertise high scores from self-designed and administered surveys of their residents. One of these commenters expressed concern that CMS is proposing to adopt an instrument developed by the very industry whose members it will be used to measure.

Response: We acknowledge that the NHCAHPS–D was developed for short-stay SNF residents [153] by the AHRQ and the CAHPS® consortium [154] in collaboration with us. We also recognize that there are other measures of resident satisfaction that are available, but we proposed the CoreQ for two primary reasons: (1) it is the only CBE endorsed survey of SNF resident satisfaction, and (2) its extensive testing prior to initial CBE endorsement in 2016 and subsequent CBE re-endorsement in 2020 and its strong item and response reliability and validity. We also considered the length of the NHCAHPS–D tool and the potential burden on respondents to complete it.

We refer the commenters to section VII.2.a.1. of this final rule where we describe how the CoreQ was developed by a *team* led by researchers from the University of Pittsburgh with input from an AHCA workgroup, providers, and residents [155] specifically for assessing satisfaction among residents and their families. Furthermore, since the measure has been endorsed by a CBE on two occasions, it means that a panel of experts and interested parties representing providers, residents, and payers support this measure for inclusion in the SNF QRP.

We also refer commenters to section VII.D. of this final rule, where we discuss the measurement gaps we identified for the SNF QRP, including the measurement concepts of resident experience and resident satisfaction. We sought feedback in the FY 2024 SNF PPS proposed rule (88 FR 21355) on the value of adding a resident experience measure, such as the NHCAHPS–D, to the SNF QRP.

Comment: Several commenters opposed the adoption of the CoreQ: SS DC measure because they believe it provides limited actionable feedback for performance improvement. One of these commenters believed that organizations tend to improve resident experiences when they have data and feedback that are actionable, which comes through measuring behaviors. They do not believe the CoreQ: SS DC measure asks about behavior and therefore fails to capture meaningful feedback. They disagree with using the CoreQ: SS DC survey because it does not ask questions about whether a specific action occurred, how often it occurred, or the quality of the action or interaction. Two commenters noted that a single score would be meaningless.

Response: We understand the commenter's concerns to be related to the fact that the CoreQ: SS DC measure represents the overall satisfaction with the nursing facility. However, we believe this to be advantageous for several reasons, including its simplicity and its utility for ranking/rating purposes.

First, the simple format may be important in helping older adults and their families choose a SNF. That is, the CoreQ: SS DC measure score is understandable. At the same time, testing demonstrated the range of CoreQ measure scores was large, indicating that the scores can be used to differentiate facilities with varying levels of customer satisfaction.[156] Second, a single score may also be useful for facilities to easily track their performance over time and a tool they might use to gauge the effectiveness of their own quality improvement processes. It is also a score a SNF could use to compare its overall level of satisfaction with other SNFs. This is something that might be much more difficult to achieve with a resident satisfaction survey that includes multiple questions about specific actions and interactions and the quality of those actions and interactions. Moreover, other resident satisfaction surveys we found were not developed or tested to produce an overall satisfaction score.

We acknowledge that the CoreQ: SS DC measure score would not provide a detailed set of information about specific actions and interactions, but a facility could have its survey vendor add as many specific questions to the survey as it wants, so it could obtain more details about why a resident responded the way they did. For more information, we refer commenters to the

[152] National Academies of Sciences, Engineering, and Medicine. 2022. *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/26526.*

[153] Sangl J, Bernard S, Buchanan J, Keller S, Mitchell N, Castle NG, Cosenza C, Brown J, Sekscenski E, Larwood D. The development of a CAHPS instrument for nursing home residents. J Aging Soc Policy. 2007;19(2):63–82. doi: 10.1300/J031v19n02_04. PMID: 17409047.

[154] The CAHPS consortium included Harvard Medical School, The RAND Corporation, and Research Triangle Institute International.

[155] Castle NG, Gifford D, Schwartz LB. The CoreQ: Development and Testing of a Nursing Facility Resident Satisfaction Survey. J Appl Gerontol. 2021 Jun;40(6):629–637. doi: 10.1177/0733464820940871. Epub 2020 Jul 29. PMID: 32723121.

[156] Castle NG, Gifford D, Schwartz LB. The CoreQ: Development and Testing of a Nursing Facility Resident Satisfaction Survey. J Appl Gerontol. 2021 Jun;40(6):629–637. doi: 10.1177/0733464820940871. Epub 2020 Jul 29. PMID: 32723121.

Draft CoreQ: SS DC Survey Protocols and Guidelines Manual found at *https://www.cms.gov/files/document/draft-coreq-ss-dc-manual508compliant.pdf.*

Comment: One commenter opposed the adoption of the CoreQ: SS DC measure because it is not currently endorsed by a CBE.

Response: We refer the commenter to section VII.C.2.a.4. of this final rule for details about the CoreQ: SS DC measure's CBE endorsement. The CoreQ: SS DC measure was initially endorsed by the CBE in 2016 and re-endorsed in 2020.[157]

Comment: One commenter noted that in the proposed rule, CMS described comments of interested parties and the Technical Expert Panel (TEP), some of whom were critical of CoreQ and whose concerns the proposed rule did not address. This commenter acknowledged that they were a member of a TEP that reviewed the CoreQ and this commenter remains extremely critical of the tool.

Response: Contrary to the commenter's assertion, we did not describe comments from a CoreQ: SS DC measure TEP in the proposed rule. As described in section VII.C.2.a.1. of the final rule, the CoreQ: SS DC survey was developed by SNFs and ALs that partnered with researchers to develop the CoreQ: SS DC survey for SNFs and ALs. TEPs are groups of experts assembled by our contractors involved in quality activities. Since neither we nor our quality measure development contractors developed the survey tool, we cannot speak to discussions that may have occurred in a provider-assembled panel associated with the measure.

However, as discussed in section VII.C.2.a.4. of this final rule, the CoreQ: SS DC measure was reviewed by the CBE's Person- and Family-Centered Care (PFCC) Committee on June 6, 2016, and subsequently the measure appeared on the List of Measures under Consideration for December 1, 2017 [158] for the SNF QRP Program. The CBE-convened MAP PAC/LTC workgroup met on December 13, 2017, and offered support of the CoreQ: SS DC measure for rulemaking, noting that it adds value by addressing a gap area for the SNF QRP.

Comment: One commenter acknowledged that it is vital to collect information on resident experience in SNFs but suggested the CoreQ: SS DC measure is not ready to be proposed for inclusion in the SNF QRP because the CoreQ questionnaire is a proprietary tool and thus requires administration by third-party vendors, as opposed to a CAHPS survey, which is maintained by the AHRQ.

Response: We agree with the commenter that it is vital to collect information on resident experience in SNFs. We do want to clarify, however, that the CoreQ: SS DC measure's survey is not a proprietary tool and is free to SNFs and vendors. All of the CoreQ surveys (along with instructions for use) are provided on a free publicly accessible website. The website does not ask for any fees for using the CoreQ surveys.

Comment: Several commenters stated that the CoreQ: SS DC measure has not been adequately tested for reliability, nor has it been tested to determine if it produces valid data or that the data are meaningful. One of these commenters stated that the fact that many facilities have ''voluntarily adopted'' CoreQ, and use it ''with ease,'' suggests that the tool is useful to facilities. However, the commenter asserted that facilities have historically used satisfaction surveys for marketing purposes, and the CoreQ's usability does not suggest that the tool is equally useful or meaningful to government regulators. Another one of these commenters noted that calculating measure scores by only including responses with an average score greater than or equal to 3.0 will impact the statistical reliability of the measure and expressed concern that this issue, combined with the low item count of only four questions, could potentially produce a measure with extremely low statistical reliability and compromising validity.

One commenter recommended that CMS use the CAHPS measures of resident and family experience which they noted are based on actual experiences and have been thoroughly tested for validity. This commenter went on to say that they disagree with CMS' conclusion that reproduction of CoreQ: SS DC survey results indicates the measure's reliability. Instead, they stated that the CoreQ's measure properties (that is, the limited number of questions in the measure, the vagueness of the questions, and the inherent bias in the scale, the computation process, and the selection process) increase the likelihood of repeated results.

Response: As described in section VII.C.2.a.(1)(b) of this final rule, the development of the CoreQ: SS DC measure involved multiple interested parties, involved rigorous testing and review on two separate occasions, and has been thoroughly vetted. Three steps were used in developing the CoreQ: SS DC questionnaire. The first step was the development of the general approach used in the questionnaire (that is, domains, format, and potential items). The data collection for this first step mostly involved using consumers in SNFs. The second step included validity testing to further refine items that should be included in the questionnaire. The data collection for this second step involved using residents in a national sample of nursing facilities. The third step included testing to examine the reliability of the CoreQ: SS DC measure (that is, facility and summary score validity). The data collection for this third step involved using residents from a national sample of nursing facilities. These three steps in the questionnaire development follow an approach used by the CAHPS nursing home surveys.[159] Since this initial testing, the CoreQ: SS DC survey has been used with tens of thousands of additional residents. The response rate and score distributions have remained in-line with the initial testing.

We acknowledge the commenter's point that SNFs have historically used satisfaction surveys for marketing purposes. However, this fact does not diminish the importance of adding a resident satisfaction measure to the SNF QRP. We recognize there are other instruments to measure SNF resident satisfaction, but no one universal instrument has been adopted by SNFs. Additionally, as described in section VII.C.2.a.(2) of this final rule, we did look at and consider other measure tools to meet this gap in the SNF QRP measure set. We decided to propose the CoreQ: SS DC measure specifically because it has been exhaustively tested for validity and reliability (as described in section VII.C.2.a.(1)(b) of this final rule) and it is endorsed by a CBE.

Comment: We received a number of comments about residents who would be excluded from receiving a CoreQ: SS DC survey. Most commenters were concerned that residents who left against medical advice (AMA) were excluded from the CoreQ: SS DC measure's denominator. As a result, they fear that residents who are may have been very dissatisfied with their care will not receive a survey. One of these commenters pointed out that residents leaving AMA are at a higher risk of adverse events and readmissions, and that SNFs could use these residents'

[157] *https://www.qualityforum.org/QPS/2614.*

[158] Centers for Medicare & Medicaid Services. List of Measures under Consideration for December 1, 2017. *https://www.cms.gov/files/document/2017amuc-listclearancerpt.pdf.*

[159] Castle NG, Gifford D, Schwartz LB. The CoreQ: Development and Testing of a Nursing Facility Resident Satisfaction Survey. J Appl Gerontol. 2021 Jun;40(6):629–637. doi: 10.1177/0733464820940871. Epub 2020 Jul 29. PMID: 32723121.

experiences and reasons for leaving in the SNF's risk management and readmission prevention strategies. This commenter also pointed out that by surveying these residents, resident feedback could highlight areas where resident-SNF communication can be improved and SNFs could identify recurring problems and implement necessary changes.

Other commenters stated that residents who transfer to another SNF, psychiatric facility, IRF, LTCH, or hospice should not be excluded either.

Two commenters also noted that residents living with Alzheimer's disease or other forms of dementia should not automatically be excluded because some residents with dementia could give meaningful opinions about their SNF stay. They maintain that CMS and the public have a significant interest in assessing the care quality provided to residents with dementia. These commenters also disagree with the exclusions for surveys completed by (i) a family member (however a resident defines ''family''), (ii) a representative of a former resident with dementia or of a resident who dies during their SNF stay, and (iii) a legal guardian of a resident under any circumstance. Another commenter referenced these exclusions as ''discriminatory,'' and stated that they are likely to skew the results to former residents who were temporarily in the facility for rehabilitation, went home, and were satisfied.

Response: We acknowledge the commenters' concerns about the CoreQ: SS DC measure exclusions. In developing the CoreQ: SS DC measure, the measure developer convened an expert panel to advise them on which exclusions to apply to the measure. The expert panel advised the measure developer to exclude residents who died, residents who were discharged to a hospital, residents with durable power of attorney for all decisions, residents on hospice, residents with low BIMS scores, and residents who left against medical advice.

Regarding the exclusion for residents who left AMA, residents who leave AMA generally do so within the first few days of admission to the SNF. As a result, the SNF has not yet had time to develop and implement a full care plan to address the resident's needs. The measure developer was not confident they could validate their answers as accurate or unbiased.

Regarding the exclusion for residents who transfer to another SNF, IRF, LTCH, or hospice, the exclusions were applied because such residents were incapable or unlikely to complete a questionnaire.

Regarding the exclusion for residents living with Alzheimer's disease or other forms of dementia, the exclusion applied in the denominator is for residents with a BIMS score of 7 or lower. A BIMS score of 7 represents residents with severe cognitive impairment, and the measure developer determined that they were unable to validate the responses as reliable, and the response rate dropped considerably in this population.

With respect to the exclusion for surveys completed by a family member, representative, legal guardian, or other proxy, the exclusion was applied because the measure developer could not be confident the responses were accurate or unbiased. However, we are intentional in our efforts to increase the resident's voice in the assessment process and SNF QRP. All residents capable of any communication should be asked to provide information for the CoreQ: SS DC measure. Self-reporting is the single most reliable indicator of resident satisfaction. For that reason, we proposed to add two additional ''help provided'' questions to the original four primary questions in the CoreQ: SS DC measure. These questions would be used by the vendor to identify and code all completed surveys where a helper assisted the respondent. A decision algorithm was proposed to determine whether a CoreQ survey would be included or excluded from the CoreQ: SS DC measure numerator based on whether a helper completed the survey for the resident or whether the helper only assisted the resident due to visual, hearing, or motor coordination impairments.[160] Residents requiring assistance only due to visual, hearing, or motor coordination impairments would be not be excluded.

Comment: Several commenters disagreed with using the CoreQ: SS DC survey because they found the number of questions to be too small, and they found the questions too vague to provide enough meaningful information for actionable improvement. One of these commenters suggested that CMS proposed a measure that is so simple that it tells consumers almost nothing about the resident's experience. This commenter, and two others, provided extensive examples of why they found each of the CoreQ: SS DC survey questions problematic. One of these commenters acknowledged that 50 questions may be very long for some residents but noted that the questions on such a survey provide much more meaningful information than the very vague four questions that constitute the CoreQ. One commenter stated the wording of the CoreQ: SS DC survey is potentially coercive in nature, implying an expected recommendation. In comparison, they noted the CAHPS Nursing Home Survey tactfully phrases similar questions to avoid such implications.

Finally, several commenters noted the CoreQ: SS DC survey does not adequately capture resident satisfaction with all types of HCP and does not represent the totality of SNF care. These commenters noted that SNF care is multifaceted, encompassing multiple disciplines and components, including activities, diet, nursing, social work, and therapies. These commenters stated that residents may have positive experiences in some aspects of their stay and negative experiences in others. One of these commenters expressed concern that the measure could potentially be gamed through a SNF's emphasis on activities that may be appealing to residents and caregivers, but do not meaningfully improve function or other outcomes. Another one of these commenters suggested that CMS should use surveyor interviews with residents, resident councils, and families to create a satisfaction score.

Response: We found the process that was used to develop the CoreQ: SS DC measure to be iterative, comprehensive, and widely published. We provide more details here and refer readers the CoreQ website at *http://coreq.org/* to learn more.

The first step of the development of the CoreQ: SS DC measure was to determine the domains, format, and potential items to include in the survey. This first step involved using consumers in nursing facilities. Following prior research in this area,[161] a literature review was conducted to examine (a) important areas of satisfaction for long-term care residents (commonly called domains), (b) response scales used, and (c) individual items used in existing surveys. The research team examined 15 commonly used satisfaction surveys and reports addressing consumer satisfaction in long-term care settings.

Next, a total of 35 domains of interest were identified. The face validity of these 35 domains was examined using nursing facility residents. That is, residents were asked to rank the importance of the domains. Residents

[160] For more details about the decision algorithm, see Chapter 8 of the CoreQ: SS DC Protocols and Guidelines Manual at *https://www.cms.gov/files/document/draft-coreq-ss-dc-manual508compliant.pdf.*

[161] Robinson, J., Lucas, J., Castle, N.G., Lowe, T.J., & Crystal, S. (2004). Consumer satisfaction in nursing homes: Current practices and resident priorities. *Research on Aging, 26*(4), 454–480.

were asked to rank only 12 of the 35 domains to help simplify the process. After analyzing the responses, there was a substantial reduction in ranking of the tenth and subsequent domains, so the nine most highly ranked domains were chosen. For the nine domains of interest, individual items (questions) were selected. That is, as many items as could be found in these domains were taken from the 15 commonly used satisfaction surveys identified previously in this section.

A list of 140 items resulted, and these were reduced in three steps. First, a team of five satisfaction survey experts, in an iterative process consisting of six rounds of consultation, identified items that most represented the domains. In each round of consultation, 100 percent agreement was used for deleting items in each domain. This process is generally known as ''Member Checking.'' [162] In the second step, the survey experts were asked to isolate individual items that measured the satisfaction of each domain globally. In each round of consultation, 100 percent agreement was used for deleting items in each domain. The items thus could potentially be used to measure overall issues in this domain, rather than more focused issues in the domain. Third, the items were further reduced, again using member checking. The five satisfaction survey experts identified items they believed to be the most easily understood by potential respondents.

The resulting items were included as part of the Pilot CoreQ: Short Stay Discharge questionnaire, which consisted of 24 items. The intent of the pilot instrument was to have items that represented the most important areas of satisfaction and to be parsimonious. Additional analyses were used to eliminate items in the Pilot instrument. The Pilot CoreQ: Short Stay Discharge questionnaire items were subsequently examined to first determine the validity of the items included and second to determine if the items could be reduced with the objective of finding the lowest number of items providing the most consumer satisfaction information.

The Pilot CoreQ: Short Stay Discharge questionnaire was then sent to 865 residents who had been discharged from a SNF in less than 100 days and who met the inclusion criteria.[163] The Pilot CoreQ: Short Stay Discharge questionnaire items were examined to determine the fewest number of items providing the most consumer satisfaction information. That is, the 24 items were examined to determine if some were globally representing the residents' overall rating of their satisfaction with the facility. Conceptually, the intent of the item reduction was to identify items (a) highly correlated with overall satisfaction, (b) having low correlations with each other, and (c) in different domains. The steps previously mentioned resulted in a short four-item instrument, the CoreQ: Short Stay Discharge questionnaire. From this instrument, a single metric was developed, the CoreQ: Short Stay Discharge measure. To determine if the 4 items in the CoreQ: Short Stay Discharge questionnaire were a reliable indicator of satisfaction, the correlation between these four items in the CoreQ: Short Stay Discharge Measure and all of the items on the Pilot CoreQ instrument was conducted. The correlation was identified as having a value of 0.94. That is, the correlation score between the final CoreQ: Short Stay Discharge Measure and all of the 22 items used in the Pilot instrument indicates that the satisfaction information is approximately the same if the survey included the four items or the 22 item Pilot instrument.

In summary, the CoreQ: SS DC measure questions were not found to be vague by the SNF residents who participated in the testing of the CoreQ survey. The CoreQ: Short Stay Discharge questionnaire was purposefully written using simple language. No *a priori* goal for reading level was set; however, a Flesch-Kinkaid scale score of six, or lower, is achieved for all questions.[164] The CoreQ: SS DC survey was developed with extensive input from residents, nursing home personnel, other survey vendors, and clinical researchers. As outlined previously in this section, the CoreQ: SS DC measure represents a resident's overall satisfaction with the SNF, including all types of HCP and SNF care. Additionally, three State Medicaid programs have incorporated the CoreQ: SS DC measure into their Medicaid quality incentive programs. As we noted before, SNFs could work with their vendors to add additional questions to their survey instrument in order to ask about other aspects of their care that they believe would help them in their quality improvement efforts.

Finally, we were unable to determine what the commenter means when they suggested the wording of the CoreQ: SS DC survey is potentially coercive in nature. The language used in the CoreQ: SS DC measure is similar to language found in other survey instruments, including the NHCAHPS–D.

Comment: One commenter was concerned that if the CoreQ: SS DC measure was implemented in the SNF QRP, it would overlap considerably with a SNF's own satisfaction survey activity. This commenter also considers the CoreQ: SS DC measure to be an imperfect gauge of care quality. Specifically, they take issue with the question that asks whether a resident's discharge needs were met. They are concerned that residents may respond based on dissatisfaction with how their discharge needs were met based on limitations of their insurance network which are beyond the control of the SNF. Therefore, they recommended CMS reconsider the elements of the CoreQ questionnaire.

Response: The CoreQ: SS DC measure could be an adjunct to a SNF's own satisfaction survey activity. As described in Chapter 6 of the Draft CoreQ: SS DC Short Stay Discharge Survey Protocols and Guidelines Manual,[165] the CoreQ: SS DC measure's set of four primary questions and two help-provided questions could be added to existing surveys used by SNFs or could be used alone to collect satisfaction information.

Regarding the comment that the CoreQ: SS DC measure is an imperfect gauge of care quality, reliability testing results at both the data element and the measure level were strong. The CoreQ: SS DC measure has a high degree of both face validity and content validity. In response to the concern that residents may respond based on dissatisfaction with how their discharge needs were met for reasons beyond the control of the SNF, we note that during the discharge planning process, it is incumbent on SNFs to make reasonable assurances that the resident's needs will be met in the next care setting.

Comment: Several commenters did not support adoption of the CoreQ: SS

[162] Creswell, J.W., & Miller, D. L. (2000). Determining validity in qualitative inquiry. *Theory into Practice, 39*(3), 124–130.

[163] The inclusion criteria for the Pilot testing is identical to the inclusion criteria for the proposed CoreQ: SS DC measure.

[164] The Flesch-Kincaid grade level readability formula analyzes and rates text based on a U.S. grade school educational level. The formula uses the average number of words per sentence and the average number of syllables per word to generate a result. A grade level score of 8.0 means that an eighth grader can understand the text. We aim for a grade level of sixth- to eighth-grade level for our notices. SSA Program Operations Manual System. NL 10605.105. *https://secure.ssa.gov/poms.nsf/lnx/0910605105*.

[165] Draft CoreQ SS DC Manual. Located in the Downloads section of the SNF QRP Measures and Technical Information web page. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information.*

DC survey because they found the response scale to be skewed and lacking objectivity.

As described in section VII.C.2.a.(1) of this final rule, the CoreQ questionnaires use a 5-point Likert scale, and the number of respondents with an average score greater than or equal to 3.0 across the four questions is divided by the total number of valid responses to yield the SNF's satisfaction score. The five responses options are: Excellent (5), Very Good (4), Good (3), Average (2), and Poor (1). These commenters objected to the fact that the scale had no middle ''neutral'' choice and believe this grading system could create bias in the survey instrument by leading the resident to a more positive response and skews the results to the positive side. One commenter questioned what the term ''average'' may mean to a resident who had only experienced care in one SNF, and as a result they would not know whether the care they received was ''average.'' This commenter was also concerned that since the term ''average'' is used as a choice, then all the other terms refer to it, so that Good (3), Very Good (4), and Excellent (5) must all be better than average under this scoring system. Another commenter provided the example that because the middle score, Good (3), is a positive response, and not a neutral answer, there is only a single negative response (Poor [1]). As a result, they believe this methodology overstates positive responses. Another commenter pointed out that CAHPS surveys use a top box score methodology and other survey-based measures may use a simple mean, but the CoreQ: SS DC measure calculates a score by using an unbalanced response scale, and only includes data from residents that provide an average rating of greater than or equal to three.

Several of these commenters also quoted the NASEM report which noted that consumer advocates and survey methodologists have raised concerns that item wording and the choice of response formats may increase the tendency of respondents to provide socially appropriate response choices and thus provide only minimal variation in the scale.[166]

Response: During the development of the CoreQ: SS DC measure, a total of 14 different scales were tested, including scales ranging from 1 to 10. Respondents were asked whether they fully understood how the response scale worked, could complete the scale, and in cognitive testing understood the scale. The scale used in the CoreQ: SS DC measure performed as well or better than the other scales tested.[167] Based on testing conducted by the measure developer at that time, as well as since the use of the CoreQ: SS DC measure by interested parties, the distribution of CoreQ scores is large, and the measure developer has not observed a ceiling effect, which would be expected if the scale only allowed for minimal variation in responses.

In response to the comment about how item wording and choice of response formats may increase the tendency of responses to provide ''socially appropriate'' response choices, the NASEM report did not reference the CoreQ specifically when making this statement, and it is unclear to us how to interpret the statement in the context of our proposal.

Comment: One commenter supported the addition of two questions to the four primary questions of the CoreQ: SS DC survey that would allow CMS to determine the level of possible intermediary assistance, and therefore, exclude only surveys that met the exclusion criteria outlined in the draft CoreQ: SS Protocols and Guidelines manual. Two commenters were concerned that a significant number of eligible residents would be excluded from the measure simply because an adult child or neighbor assists with completion of the survey. These commenters pointed out that a number of residents served in a SNF face limitations and if they need assistance from a family member or trusted friend to complete the CoreQ: SS DC survey, they should not be excluded from the data files.

Response: We thank the commenter for their support of the two additional helper provided questions to determine the level of possible intermediary assistance a resident receives when completing the CoreQ: SS DC measure survey. Additionally, just because a resident is assisted by an adult child or neighbor does not mean they would automatically be excluded. As described in Chapter 8 of the Draft CoreQ: SS DC Protocols and Guidelines Manual, a decision algorithm would be used to determine whether a CoreQ survey is included or excluded from the CoreQ: SS DC measure denominator based on whether a helper completed the survey for the resident or whether the helper only assisted the resident due to visual, hearing, or motor coordination impairments.[168] Residents would not be automatically excluded just because they required assistance with reading the survey, having the survey translated into their own primary language, or completing the mailed survey due to physical impairments.

Comment: Two commenters suggested that most SNF residents require in-person interviews for data collection because many residents have vision, hearing, and cognitive problems. They stated CMS' plan does not allow for adequate data sampling and data collection and could result in biased results.

Response: As discussed in the Draft CoreQ: SS DC Survey Protocols and Guidelines Manual,[169] CMS-approved CoreQ survey vendors would be required to offer a toll-free assistance line and an electronic mail address which respondents could use to seek help with completing the survey. Additionally, residents could ask a family member or friend to assist them by reading the survey to them or translating the survey into their primary language. Such methods of assisted data collection have been used successfully for surveys in other PAC settings, including home health agencies.

Comment: Several commenters opposed the use of imputing a response to obtain a score when only one of the questions is missing a response. One of these commenters noted that imputation for missing data is appropriate only if it is assumed that all measures are equivalent or redundant to each other and the sum of the remaining responses can ''stand in'' for missing data. The commenter suggested that if individual measures are intended to address unique facets of experience, or if different populations or groups of respondents might have reason to skip particular items, imputation would be inappropriate and misleading. Another one of these commenters suggested that survey questionnaires with missing data should be discarded.

Response: We appreciate the concerns that some commenters may have with

[166] National Academies of Sciences, Engineering, and Medicine. 2022. *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/26526.*

[167] Castle NG, Gifford D, Schwartz LB. The CoreQ: Development and Testing of a Nursing Facility Resident Satisfaction Survey. J Appl Gerontol. 2021 Jun;40(6):629–637. doi: 10.1177/0733464820940871. Epub 2020 Jul 29. PMID: 32723121.

[168] For more details about the decision algorithm, see Chapter 8 of the Draft CoreQ: SS DC Protocols and Guidelines Manual at *https://www.cms.gov/files/document/draft-coreq-ss-dc-manual508compliant.pdf.*

[169] Available on the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/qualityinitiatives-patient-assessmentinstruments/nursinghomequalityinits/skilled-nursing-facility-qualityreporting-program/snf-quality-reportingprogram-measures-and-technicalinformation.*

imputation of a missing score. However, the measure developer tested the imputation method as part of their overall measure development process. Two methods of imputing missing data were tested: (1) using the average value from the three available questions as the imputed value, and (2) using the lowest value from the three available questions as the imputed value. They found that imputing the average score or imputing the lowest score had no influence on the overall CoreQ measure scores for SNFs.[170] The measure developer also correlated cases with one missing value imputed and cases with no missing values with quality indicators (that is, restraint use, pressure ulcers, catheter use, antipsychotic use, antidepressant use, antianxiety use, use of hypnotics, and deficiency citations). They found the correlation with these quality indicators unchanged and therefore bias from imputation was minimal.[171]

Comment: While one commenter believed a short stay discharge measure is long overdue within the SNF QRP, they stated that CMS should first provide additional guidance on how it will benchmark and/or risk-adjust the measure among SNFs and over time. They stated any final methodology must factor in improvements over time, and not just the absolute score relative to all SNFs or even a smaller cohort of peers. This commenter recommended that CMS also carefully consider whether/which kinds of SNFs will perform well or poorly depending on multiple variables. They stated that facilities in underserved areas with high prevalence of social determinants of health (SDOH) and predominated by SNFs with lower star ratings will not perform well on measures of resident satisfaction, resulting in exacerbation of access in underserved communities. Another commenter is concerned that the measure is not risk-adjusted.

Response: As described in section VII.C.2.a.(5)(b) of this final rule, the CoreQ: SS DC measure is not risk-adjusted by resident level sociodemographic status (SDS) variables, as the measure steward found no statistically significant differences (at the 5 percent level) in scores between the SDS variables.[172] We do reevaluate measures implemented in the SNF QRP on an ongoing basis to ensure they have strong scientific acceptability as well as appropriately capture the care provided by SNFs. Lastly, we take the appropriate access to care in SNFs very seriously and monitor closely to determine whether new SNF QRP measures have unintended consequences on access to care for high-risk residents.

Comment: One commenter disagreed with how the CoreQ: SS DC measure is calculated. They believe that since it only includes respondents that have an average score greater than or equal to 3.0 and then dividing that number by the total number of valid responses to the survey that SNFs will only be incentivized to drive improvement from Poor or Average to Good. They stated the methodology used to calculate a score for the CoreQ: SS DC measure is inconsistent with the calculations of other measures used by CMS and generally viewed as statistically unreliable. Another commenter was concerned that the CoreQ: SS DC survey focuses less on rating the quality of resident experience and more on summative satisfaction ratings.

Response: We do not agree with the commenter that the CoreQ: SS DC measure score will only incentivize SNFs to drive improvement from Poor or Average to Good. The CoreQ: SS DC measure is expressed as the percentage of the SNF short stay population whose average score is three or higher. Other SNF QRP measures are also expressed as the percentage of the SNF population who meet or exceed a threshold.[173]

We believe that the CBE endorsed CoreQ: SS DC measure has been extensively tested and is highly reliable, valid, and reportable, and would fill a critical measurement gap within the SNF QRP. However, we acknowledge the concerns raised by commenters that the CoreQ: SS DC measure may not have enough questions to adequately measure residents' satisfaction with the quality of care received by SNFs. We also recognize the concerns raised by commenters that finalizing the CoreQ: SS DC measure would require SNFs to contract with a survey vendor and implement a workflow to create and send a resident information file (RIF) to the vendor on a weekly basis. Therefore, after consideration of the public comments we received on this proposal, we have decided that at this time, we will not finalize the proposal to add the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP. However, we remain committed to the timely adoption of a meaningful measure that addresses resident satisfaction or resident experience for the SNF QRP. As we stated in the FY 2024 SNF PPS proposed rule (88 FR 21344), there is currently no national standardized satisfaction questionnaire that measures a resident's satisfaction with the quality of care received in SNFs. While it may require time to conduct further research to identify and/or develop a meaningful measure that meets the needs of both SNFs and consumers, we intend to propose a resident satisfaction or resident experience measure for the SNF QRP in future rulemaking.

b. COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2026 SNF QRP

(1) Background

COVID–19 has been and continues to be a major challenge for PAC facilities, including SNFs. The Secretary first declared COVID–19 a PHE on January 31, 2020. As of June 19, 2023, the U.S. has reported 103.9 million cases of COVID–19 and 1.13 million deaths due to COVID–19.[174] Although all age groups are at risk of contracting COVID–19, older persons are at a significantly higher risk of mortality and severe disease following infection; those over age 80 dying at five times the average rate.[175] Older adults, in general, are prone to both acute and chronic infections owing to reduced immunity, and are a high-risk population.[176]

[170] Castle NG, Gifford D, Schwartz LB. The CoreQ: Development and Testing of a Nursing Facility Resident Satisfaction Survey. J Appl Gerontol. 2021 Jun;40(6):629–637. doi: 10.1177/0733464820940871. Epub 2020 Jul 29. PMID: 32723121. CoreQ_Short_Stay_Testing_Final_v7.1_Corrected_4_20_20_FinalforSubmission-637229958835088042.docx. Available in the measure's specifications from the Patient Experience and Function Spring Cycle 2020 project. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/36/Spring/2020/measures/2614/shared/2614.zip.*

[171] CoreQ_Short_Stay_Testing_Final_v7.1_Corrected_4_20_20_FinalforSubmission-637229958835088042.docx. Available in the measure's specifications from the Patient Experience and Function Spring Cycle 2020 project. *https://nqfappservicesstorage.blob.core.windows.net/proddocs/36/Spring/2020/measures/2614/shared/2614.zip.*

[172] The measure developer examined the following SDS categories: age, race, gender, and highest level of education. CoreQ: Short Stay Discharge Measure.

[173] Examples include: (1) The Discharge Self-Care Score measure and Discharge Mobility Score measure are expressed as the percentage of SNF patients who meet or exceed an expected discharge score, and (2) The Drug Regimen Review measure is expressed as the number of patients who received a drug regimen review at admission and throughout their Part A stay and when a potentially clinically significant issue was found, it was addressed bv midnight of the next calendar day.

[174] Centers for Disease Control and Prevention. COVID Data Tracker. *https://covid.cdc.gov/covid-data-tracker/#cases_totalcases.* June 19, 2023.

[175] United Nations. Policy Brief: The Impact of COVID–19 on Older Persons. May 2020. *https://unsdg.un.org/sites/default/files/2020-05/Policy-Brief-The-Impact-of-COVID-19-on-Older-Persons.pdf.*

[176] Lekamwasam R, Lekamwasam S. Effects of COVID–19 Pandemic on Health and Wellbeing of Older People: a Comprehensive Review. *Ann*

Adults age 65 and older comprise over 75 percent of total COVID–19 deaths despite representing 13.4 percent of reported cases.[177] COVID–19 has impacted older adults' access to care, leading to poorer clinical outcomes, as well as taking a serious toll on their mental health and well-being due to social distancing.[178]

Since the development of the vaccines to combat COVID–19, studies have shown they continue to provide strong protection against severe disease, hospitalization, and death in adults, including during the predominance of Omicron BA.4 and BA.5 variants.[179] Initial studies showed the efficacy of FDA-approved or authorized COVID–19 vaccines in preventing COVID–19. Prior to the emergence of the Delta variant of the virus, vaccine effectiveness against COVID–19-associated hospitalizations among adults age 65 and older was 91 percent for those who were fully vaccinated with a full mRNA vaccination (Pfizer-BioNTech or Moderna), and 84 percent for those receiving a viral vector vaccine (Janssen). Adults age 65 and older who were fully vaccinated with an mRNA COVID–19 vaccine had a 94 percent reduction in risk of COVID–19 hospitalizations, while those who were partially vaccinated had a 64 percent reduction in risk.[180] Further, after the emergence of the Delta variant, vaccine effectiveness against COVID–19-associated hospitalizations for adults who were fully vaccinated was 76 percent among adults age 75 and older.[181]

More recently, since the emergence of the Omicron variants and the availability of booster doses, multiple studies have shown that while vaccine effectiveness has waned, protection is higher among those receiving booster doses than among those receiving only the primary series.[182] [183] [184] CDC data show that, among people age 50 and older, those who have received both a primary vaccination series and booster doses have a lower risk of hospitalization and dying from COVID–19 than their non-vaccinated counterparts.[185] Additionally, a second vaccine booster dose has been shown to reduce risk of severe outcomes related to COVID–19, such as hospitalization or death, among nursing home residents. Nursing home residents who received their second booster dose were more likely to have additional protection against severe illness compared to those who received only one booster dose after their initial COVID–19 vaccination.[186] Early evidence also demonstrates that the bivalent boosters, specifically aimed to provide better protection against disease caused by Omicron subvariants, have been quite effective, and underscores the role of up to date vaccination protocols in effectively countering the spread of COVID–19.[187] [188]

(a) Measure Importance

Despite the availability and demonstrated effectiveness of COVID–19 vaccinations, significant gaps continue to exist in vaccination rates.[189] As of March 22, 2023, vaccination rates among people age 65 and older are generally high for the primary vaccination series (94.3 percent) but lower for the first booster (73.6 percent among those who received a primary series) and even lower for the second booster (59.9 percent among those who received a first booster).[190] Additionally, though the uptake in boosters among people age 65 and older has been much higher than among people of other ages, booster uptake still remains relatively low compared to primary vaccination among older adults.[191] Variations are also present when examining vaccination rates by race, gender, and geographic location.[192] For example, 66.2 percent of the Asian, non-Hispanic population have completed the primary series and 21.2 percent have received a bivalent booster dose, whereas 44.9 percent of the Black, non-Hispanic population have completed the primary series and only 8.9 percent have received the bivalent booster dose. Among Hispanic populations, 57.1 percent of the population have completed the primary series and 8.5 percent have received the bivalent booster dose, while in White, non-Hispanic populations, 51.9 percent have completed the primary series and 16.2 percent have received a bivalent

Geriatr Med Res. 2020;24(3):166–172. doi: 10.4235/agmr.20.0027. PMID: 32752587; PMCID: PMC7533189.

[177] Centers for Disease Control and Prevention. Demographic Trends of COVID–19 Cases and Deaths in the U.S. Reported to CDC. COVID Data Tracker. *https://covid.cdc.gov/covid-data-tracker/#demographics.*

[178] United Nations. Policy Brief: The Impact of COVID–19 on Older Persons. May 2020. *https://unsdg.un.org/sites/default/files/2020-05/Policy-Brief-The-Impact-of-COVID-19-on-Older-Persons.pdf.*

[179] Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine Against COVID–19. *N Engl J Med.* 2022 Oct 6;387(14):1279–1291. doi: 10.1056/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

[180] Centers for Disease Control and Prevention. Fully Vaccinated Adults 65 and Older Are 94% Less Likely to Be Hospitalized with COVID–19. April 28, 2021. *https://www.cdc.gov/media/releases/2021/p0428-vaccinated-adults-less-hospitalized.html.*

[181] Interim Estimates of COVID–19 Vaccine Effectiveness Against COVID–19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS–CoV–2 B.1.617.2 (Delta) Variant Predominance—Nine States, June–August 2021. (Grannis SJ, et al. *MMWR Morb Mortal Wkly Rep.* 2021;70(37):1291–1293. doi: 10.15585/mmwr.mm7037e2). *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e2.htm.*

[182] Surie D, Bonnell L, Adams K, et al. Effectiveness of monovalent mRNA vaccines against COVID–19–associated hospitalization among immunocompetent adults during BA.1/BA.2 and BA.4/BA.5 predominant periods of SARS–CoV–2 Omicron variant in the United States—IVY Network, 18 States, December 26, 2021–August 31, 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71(42):1327–1334. doi: 10.15585/mmwr.mm7142a3.

[183] Andrews N, Stowe J, Kirsebom F, et al. Covid–19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant. *N Engl J Med.* 2022;386(16):1532–1546. doi: 10.1056/NEJMoa2119451. PMID: 35249272; PMCID: PMC8908811.

[184] Buchan SA, Chung H, Brown KA, et al. Estimated Effectiveness of COVID–19 Vaccines Against Omicron or Delta Symptomatic Infection and Severe Outcomes. *JAMA Netw Open.* 2022;5(9):e2232760. doi:10.1001/jamanetworkopen.2022.32760. PMID: 36136332; PMCID: PMC9500552.

[185] Centers for Disease Control and Prevention. Rates of laboratory-confirmed COVID–19 hospitalizations by vaccination status. COVID Data Tracker. 2023, February 9. Last accessed March 22, 2023. *https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination.*

[186] Centers for Disease Control and Prevention. COVID–19 Vaccine Effectiveness Monthly Update. COVID Data Tracker. November 10, 2022. *https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness.*

[187] Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine Against COVID–19. *N Engl J Med.* 2022 Oct 6;387(14):1279–1291. doi: 10.1056/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

[188] Tan, S.T., Kwan, A.T., Rodríguez-Barraquer, I. et al. Infectiousness of SARS–CoV–2 breakthrough infections and reinfections during the Omicron wave. Nat Med 29, 358–365 (2023). *https://doi.org/10.1038/s41591-022-02138-x.*

[189] Centers for Disease Control and Prevention. COVID–19 Vaccinations in the United States. COVID Data Tracker. *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5.*

[190] Centers for Disease Control and Prevention. COVID–19 Vaccination Age and Sex Trends in the United States, National and Jurisdictional. *https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Age-and-Sex-Trends-in-the-Uni/5i5k-6cmh.*

[191] Freed M, Neuman T, Kates J, Cubanski J. Deaths Among Older Adults Due to COVID–19 Jumped During the Summer of 2022 Before Falling Somewhat in September. Kaiser Family Foundation. October 6, 2022. *https://www.kff.org/coronavirus-covid-19/issue-brief/deaths-among-older-adults-due-to-covid-19-jumped-during-the-summer-of-2022-before-falling-somewhat-in-september/.*

[192] Saelee R, Zell E, Murthy BP, et al. Disparities in COVID–19 Vaccination Coverage Between Urban and Rural Counties—United States, December 14, 2020–January 31, 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71:335–340. doi: 10.15585/mmwr.mm7109a2.

booster dose.[193] Disparities have been found in vaccination rates between rural and urban areas, with lower vaccination rates found in rural areas.[194] [195] Data show that 55.2 percent of the eligible population in rural areas have completed the primary vaccination series, as compared to 66.5 percent of the eligible population in urban areas.[196] Receipt of bivalent booster doses among those eligible has been lower: 18 percent of the urban population have received a booster dose, and 11.5 percent of the rural population have received a booster dose.[197]

We proposed to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure for the SNF QRP beginning with the FY 2026 SNF QRP. The proposed measure has the potential to increase COVID–19 vaccination coverage of residents in SNFs, as well as prevent the spread of COVID–19 within the SNF resident population. This measure would also support the goal of the CMS Meaningful Measure Initiative 2.0 to ''Empower consumers to make good health care choices through patient-directed quality measures and public transparency objectives.'' The proposed Patient/Resident COVID–19 Vaccine measure would be reported on Care Compare and would provide residents and caregivers, including those who are at high risk for developing serious complications from COVID–19, with valuable information they can consider when choosing a SNF. The proposed Patient/Resident COVID–19 Vaccine measure would also facilitate resident care and care coordination during the hospital discharge planning process. A discharging hospital, in collaboration with the resident and family, could use this proposed measure's information on Care Compare to coordinate care and ensure resident preferences are considered in the discharge plan. Additionally, the proposed Patient/Resident COVID–19 Vaccine measure would be an indirect measure of SNF action. Since the resident's COVID–19 vaccination status would be reported at discharge from the SNF, if a resident is not up to date with their COVID–19 vaccine per applicable CDC guidance at the time they are admitted, the SNF has the opportunity to educate the resident and provide information on why they should become up to date with their COVID–19 vaccine. SNFs may also choose to administer the vaccine to the resident prior to their discharge from the SNF or coordinate a follow-up visit for the resident to obtain the vaccine at their physician's office or local pharmacy.

(b) Item Testing

Our measure development contractor conducted testing of the proposed standardized patient/resident COVID–19 vaccination coverage assessment item for the Patient/Resident COVID–19 Vaccine measure using resident scenarios, draft guidance manual coding instructions, and cognitive interviews to assess SNFs' comprehension of the item and the associated guidance. A team of clinical experts assembled by our measure development contractor developed these resident scenarios to represent the most common scenarios that SNFs would encounter. The results of the item testing demonstrated that SNFs that used the draft guidance manual coding instructions had strong agreement (that is, 84 percent) with the correct responses, supporting its reliability. The testing also provided information to improve both the item itself and the accompanying guidance.

(2) Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, each measure specified under section 1899B of the Act be endorsed by a CBE with a contract under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a CBE identified by the Secretary. The proposed Patient/Resident COVID–19 Vaccine measure is not CBE endorsed and, after review of other measures endorsed or adopted by consensus organizations, we were unable to identify any measures endorsed or adopted by consensus organizations for SNFs focused on capturing COVID–19 vaccination coverage of SNF residents. We found only one related measure addressing COVID–19 vaccination, the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure, adopted for the FY 2023 SNF QRP (86 FR 42480 through 42489), which captures the percentage of HCP who receive a complete COVID–19 primary vaccination series, but not booster doses.

Although SNFs' COVID–19 vaccination rates are posted on Care Compare, these data are aggregated at the facility level, and SNFs are not required to report beneficiary-level data to the CDC's NHSN. The COVID–19 vaccination rates currently posted on Care Compare are obtained from CDC's NHSN and reflect ''residents who completed primary vaccination series'' and ''residents who are up-to-date on their vaccines'' across the entire nursing home (NH) resident population. Residents receiving SNF care under the Medicare fee-for-service program differ from residents receiving long-term care in nursing homes in several ways. SNF residents typically enter the facility after an inpatient hospital stay for temporary specialized post-acute care, while NH residents typically have chronic or progressive medical conditions, requiring maintenance and supportive levels of care, and may reside in the NH for years. Additionally, the SNF QRP includes data submitted by non-CAH swing bed units whose data are only represented through the SNF QRP and are not included in the COVID–19 vaccination data reported to the NHSN by nursing homes. The proposed Patient/Resident COVID–19 Vaccine measure would be calculated using data collected on the MDS (as described in section VI.F.4. of the FY 2024 SNF proposed rule) at the beneficiary level, which would enhance SNFs' ability to monitor their own infection prevention efforts with information on which they can act.

Additionally, the COVID–19 reporting requirements set forth in 42 CFR 483.80(g), finalized in the interim final rule with comment period (IFC) published on May 13, 2021 entitled ''Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff''

[193] Centers for Disease Control and Prevention. Trends in Demographic Characteristics of People Receiving COVID–19 Vaccinations in the United States. COVID Data Tracker. 2023, January 20. Last accessed January 17, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends.*

[194] Saelee R, Zell E, Murthy BP, et al. Disparities in COVID–19 Vaccination Coverage Between Urban and Rural Counties—United States, December 14, 2020–January 31, 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71:335–340. doi: 10.15585/mmwr.mm7109a2.

[195] Sun Y, Monnat SM. Rural-Urban and Within-Rural Differences in COVID–19 Vaccination Rates. *J Rural Health.* 2022;38(4):916–922. doi: 10.1111/jrh.12625. PMID: 34555222; PMCID: PMC8661570.

[196] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023, January 20. Last accessed January 17, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity.*

[197] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023, January 20. Last accessed January 17, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity.*

(86 FR 26315 through 26316) (hereafter referred to as the May 2021 IFC) are directed at the LTC facilities' requirements and are separate from the SNF QRP. The purpose of the May 2021 IFC was to collect information which would allow the CDC to identify and alert us to facilities that may need additional support in regard to vaccine administration and education. While the COVID–19 staff vaccination requirements are being withdrawn from the Conditions of Participation, SNFs must continue to educate and offer the COVID–19 vaccine to their residents, clients, and staff, as well as perform the appropriate documentation for these activities.[198]

The purpose of the proposed Patient/Resident COVID–19 Vaccine measure is to allow for the collection of resident vaccination data under the SNF QRP and subsequent public reporting of SNFs' facility-level resident vaccination rates on Care Compare so that Medicare beneficiaries who require short stays can make side-by-side SNF comparisons. Adoption of the proposed measure would also promote measure harmonization across quality reporting programs and provide Medicare beneficiaries the information to make side-by-side comparisons across other facility types to facilitate informed decision making in an accessible and user-friendly manner. Finally, the proposed Patient/Resident COVID–19 Vaccine measure would generate actionable data on vaccination rates that can be used to target quality improvement among SNFs.

Therefore, after consideration of other available measures that assess COVID–19 vaccination rates among SNF residents, we believe the exception under section 1899B(e)(2)(B) of the Act applies. We intend to submit the proposed measure to the CBE for consideration of endorsement when feasible.

(3) Interested Parties and Technical Expert Panel (TEP) Input

First, the measure development contractor convened a focus group of patient and family/caregiver advocates (PFAs) to solicit input. The PFAs believed a measure capturing raw vaccination rate, irrespective of SNF action, would be most helpful in resident and caregiver decision-making. Next, TEP meetings were held on November 19, 2021, and December 15, 2021 to solicit feedback on the development of patient/resident COVID–19 vaccination measures and assessment items for the PAC settings. The TEP panelists voiced their support for PAC patient/resident COVID–19 vaccination measures and agreed that developing a measure to report the rate of vaccination in a SNF/NH setting without denominator exclusions was an important goal. We considered the TEP's recommendations, and we applied the recommendations, where technically feasible and appropriate. A summary of the TEP proceedings titled *Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report*[199] is available on the CMS MMS Hub.

To seek input on the importance, relevance, and applicability of a patient/resident COVID–19 vaccination coverage measure, we solicited public comments in an RFI for publication in the FY 2023 SNF PPS proposed rule (87 FR 42424). Commenters were mixed on whether they supported the concept of a measure addressing COVID–19 vaccination coverage among SNF residents. Two commenters noted the measure should account for other variables, such as whether the vaccine was offered, as well as excluding residents with medical contraindications to the vaccine (87 FR 47553).

(4) Measure Applications Partnership (MAP) Review

In accordance with section 1890A of the Act, the pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List, that the Secretary is considering adopting for use in Medicare programs. This allows interested parties to provide recommendations to the Secretary on the measures included on the list. The Patient/Resident COVID–19 Vaccine measure was included on the publicly available 2022 MUC List for the SNF QRP.[200]

After the MUC List was published, MAP received seven comments by interested parties during the measure's MAP pre-rulemaking process. Commenters were mostly supportive of the measure and recognized the importance of resident COVID–19 vaccination, and that measurement and reporting is one important method to help healthcare organizations assess their performance in achieving high rates of up to date vaccination. One commenter also noted that resident engagement is critical at this stage of the pandemic because best available information indicates COVID–19 variants will continue to require additional boosters to avert case surges. Another commenter noted the benefit of less-specific criteria for inclusion in the numerator and denominator of the proposed Patient/Resident COVID–19 Vaccine measure, which would provide flexibility for the measure to remain relevant to current circumstances. Several commenters noted their conditional support, however, and raised several issues about the measure. Specifically, one questioned whether our intent was to replace the required NHSN reporting if this measure were finalized and noted it did not collect data on Medicare Advantage residents. Another commenter suggested that nursing homes might refuse to admit unvaccinated residents, and was concerned about the costs SNFs would incur purchasing the vaccines. Another commenter raised concerns about the measure since it did not directly measure provider actions to increase vaccine uptake in the numerator and that it would only collect vaccination information on Medicare fee-for-service residents, rather than all residents, regardless of payer. Finally, one commenter was concerned because there were no exclusions for residents who refused to become up to date with their COVID–19 vaccination.

Subsequently, several MAP workgroups met to provide input on the measure. First, the MAP Health Equity Advisory Group convened on December 6, 2022. One MAP Health Equity Advisory Group member noted that the percentage of true contraindications for the COVID–19 vaccine is low, and the lack of exclusions on the measure is reasonable in order to minimize

[198] Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements (88 FR 36502).

[199] *Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report* is available on the CMS MMS Hub at *https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf.*

[200] CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and Recommendation Reports. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

variation in what constitutes a contraindication.[201] The MAP Rural Health Advisory Group met on December 8, 2022, and requested clarification of the term ''up to date'' and noted concerns with the perceived level of burden for collection of data.[202]

Next, the MAP PAC/LTC workgroup met on December 12, 2022. The voting workgroup members noted the importance of reporting residents' vaccination status, but discussed their concerns about: (1) the duplication of data collection with the NHSN if an assessment-based measure were adopted into the SNF QRP; (2) how publicly reported rates would differ from the rates reported by the NHSN; (3) that the Patient/Resident COVID–19 Vaccine measure does not account for resident refusals or those who are unable to respond; and (4) the difficulty of implementing the definition of ''up to date.'' We clarified during the PAC/LTC workgroup meeting that this measure was intended to only include Medicare Part A-covered SNF stays. We further noted that the proposed Patient/Resident COVID–19 Vaccine measure does not have exclusions for resident refusals because the proposed measure was intended to report raw rates of vaccination. We explained that raw rates of vaccination collected by the proposed Patient/Resident COVID–19 Vaccine measure are important for consumer choice and PAC providers, including SNFs, are in a unique position to leverage their care processes to increase vaccination coverage in their settings to protect residents and prevent negative outcomes. We also clarified that the measure defines ''up to date'' in a manner that provides flexibility to reflect future changes in the CDC's guidance with respect to COVID–19 vaccination. Finally, we clarified that, like the existing HCP COVID–19 Vaccine measure, this measure would continue to be reported quarterly because the CDC has not yet determined whether COVID–19 is seasonal. Ultimately, the PAC/LTC workgroup did not achieve a 60 percent consensus vote to accept the CBE's preliminary analysis assessment of conditional support for the Patient/Resident COVID–19 Vaccine measure for SNF QRP rulemaking pending testing demonstrating the measure is reliable and valid, and CBE endorsement.[203] Since the PAC/LTC workgroup did not reach consensus to accept, or subsequently to overturn the CBE staff's preliminary analysis assessment, the preliminary analysis assessment became the final recommendation of the PAC/LTC workgroup.

The CBE received 10 comments by interested parties in response to the PAC/LTC workgroup recommendations. Interested parties generally understood the importance of COVID–19 vaccinations' role in preventing the spread of COVID–19 infections, although a majority of commenters did not recommend the inclusion of the proposed Patient/Resident COVID–19 Vaccine measure in the SNF QRP and raised several concerns. Specifically, several commenters were concerned about vaccine hesitancy, SNFs' inability to influence measure results based on factors outside of their control, duplication with NHSN reporting requirements, data lag in public reporting of QRP data relative to NHSN's current reporting of the measure, and that the proposed Patient/Resident COVID–19 Vaccine measure is not representative of the full SNF population, noting that the proposed Patient/Resident COVID–19 Vaccine measure has not been fully tested, and encouraged us to monitor the measure for unintended consequences and ensure that the measure has meaningful results. One commenter was in support of the proposed Patient/Resident COVID–19 Vaccine measure and provided recommendations for us to consider, including an exclusion for medical contraindications and submitting the measure for CBE endorsement. Another commenter questioned why the PAC/LTC workgroup recommendation for SNF was not consistent with their recommendation for the proposed Patient/Resident COVID–19 Vaccine measure in other PAC QRPs.

Finally, the MAP Coordinating Committee convened on January 24, 2023, and noted concerns which were previously discussed in the PAC/LTC workgroup, such as the duplication of NHSN reporting requirements and potential for selection bias based on the resident's vaccination status. We were able to clarify that this measure was intended to include only Medicare Part A-covered SNF stays for facilities required to report to the SNF QRP, since the Medicare Advantage resident population is not part of the SNF QRP reporting requirements. We also noted that this measure does not have exclusions for resident refusals since this is a process measure intended to report raw rates of vaccination and is not intended to be a measure of SNFs' actions. We acknowledged that a measure accounting for variables, such as SNFs' actions to vaccinate residents, could be important, but noted that we are focused on a measure which would provide and publicly report vaccination rates for consumers given the importance of this information to residents and their caregivers.

The MAP Coordinating Committee recommended three mitigation strategies for the Patient/Resident COVID–19 Vaccine measure: (i) reconsider exclusions for medical contraindications, (ii) complete reliability and validity measure testing, and (iii) seek CBE endorsement. The Coordinating Committee ultimately reached 90 percent consensus on its recommendation of ''Do not Support with potential for mitigation.'' [204] Despite the MAP Coordinating Committee's vote, we believe it is still important to propose the Patient/Resident COVID–19 Vaccine measure for the SNF QRP. As we stated in section VI.C.2.b.(3) of the FY 2024 SNF PPS proposed rule, we did not include exclusions for medical contraindications because the PFAs we met with told us that a measure capturing raw vaccination rate, irrespective of any medical contraindications, would be most helpful in resident and family/caregiver decision-making. We do plan to conduct reliability and validity measure testing once we have collected enough data, and we intend to submit the proposed measure to the CBE for consideration of endorsement when feasible. We refer readers to the final MAP recommendations, titled *2022–2023 MAP Final Recommendations*.[205]

(5) Quality Measure Calculation

The proposed Patient/Resident COVID–19 Vaccine measure is a process measure that reports the percent of stays in which residents in a SNF are up to date on their COVID–19 vaccinations

[201] CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and Recommendation Reports. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[202] CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[203] National Quality Forum MAP Post-Acute Care/Long Term Care Workgroup Materials. Meeting Summary—MUC Review Meeting. Accessed January 20, 2023. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97960.*

[204] National Quality Forum Measure Applications Partnership. 2022–2023 MAP Final Recommendations. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=98102.*

[205] 2022–2023 MAP Final Recommendations. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

per the CDC's latest guidance.[206] This measure has no exclusions, and is not risk adjusted.

The numerator for this measure would be the total number of Medicare Part A-covered SNF stays in which residents are up to date with their COVID–19 vaccine per CDC's latest guidance during the reporting year. The denominator for this measure would be the total number of Medicare Part A-covered SNF stays discharged during the reporting period. For the SNF QRP, this would apply to all freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals.

The data source for the proposed Patient/Resident COVID–19 Vaccine measure is the MDS assessment instrument for SNF residents. For more information about the proposed data submission requirements for this measure, we refer readers to section VII.F.4. of this final rule. For additional technical information about this proposed measure, we refer readers to the draft measure specifications document titled *Patient-Resident-COVID-Vaccine-Draft-Specs.pdf*[207] available on the SNF QRP Measures and Technical Information web page.

We solicited public comments on our proposal to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 SNF QRP. The following is a summary of the comments we received on our proposal to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 SNF QRP and our responses.

Comment: A number of commenters supported the adoption of this measure into the SNF QRP because of the importance to the safety of residents. Commenters agreed that this measure would provide another source of valuable information to current and prospective SNF residents and their family/caregivers in their decision-making process. One commenter suggested that rather than remaining specific to COVID–19, the measure could be revised to include all CDC-recommended vaccines. Two commenters also appreciated that collection of this data would only require minimal burden since it consists of only one MDS item on the discharge assessment and the item is similar to the existing resident influenza vaccination item.

Response: We thank the commenters for their support and agree that the Patient/Resident COVID–19 Vaccine measure would provide residents and caregivers, including those who are at high risk for developing serious complications from COVID–19, with valuable information they can consider when choosing a SNF. We also agree with the commenter that the measure would not add significant burden since the data item would consist of a single MDS item and SNFs would be able to use multiple sources of information available to obtain the vaccination data, such as resident interviews, medical records, proxy response, and vaccination cards provided by the resident or their caregivers. We would also publish coding guidance for the new item and SNFs will also have access to guidance from the CDC to further aid their collection of these data.[208] Finally, we appreciate the commenter's suggestion that the measure could be revised to include all CDC-recommended vaccines and will use this input to inform our future measure development efforts.

Comment: Several commenters stated that the proposed measure was not a measure of quality of care because it did not reflect provider action. They noted that there may be medical, religious, and/or cultural reasons for a resident's decision not to receive a vaccine that are out of a SNF's control. One commenter noted that it is possible for a SNF to have a robust effort to encourage vaccination among its patients/residents, but still have a relatively low rate of vaccination. Another commenter noted that resident vaccination may also be influenced by political beliefs and the political environment in a resident's region. One commenter noted that continuing disparities in vaccine uptake do not reflect the local SNFs' efforts to bring their residents up to date, but often reflect differences deeply rooted in culture, religion, ethnicity, socioeconomic status, and more. Some commenters pointed out that residents have the right to refuse vaccination, in the same way they have the right to refuse other medical and nursing interventions.

Response: While we agree with the commenters that residents have the right to refuse vaccination, we disagree with the commenters who suggested the proposed Patient/Resident COVID–19 Vaccine measure is an invalid measure of quality of care. On the contrary, we believe it would be a beneficial addition to the other vaccination measures in the SNF QRP. We believe it is an indirect measure of provider action since SNFs have the opportunity to encourage, as well as coordinate, vaccinations among residents. This is particularly important for residents at SNFs, who tend to be older and thus more vulnerable to serious complications from COVID–19. CDC data show that, among people age 50 and older, those who have received both a primary vaccination series and booster doses have a lower risk of hospitalization and dying from COVID–19 than their non-vaccinated counterparts.[209] Additionally, a second vaccine booster dose has been shown to reduce risk of severe outcomes related to COVID–19, such as hospitalization or death, among nursing home residents. Nursing home residents who received their second booster dose were more likely to have additional protection against severe illness compared to those who received only one booster dose after their initial COVID–19 vaccination.[210]

We acknowledge that individual residents have a choice regarding whether to receive a COVID–19 vaccine or booster dose(s), but residents and their caregivers also have choices about selecting PAC providers, and it is our role to empower them with the information they need to make an informed decision by publicly reporting the data we receive from SNFs on this measure. We understand that despite a SNF's best efforts, there may be instances where a resident may choose not to receive a booster dose of the COVID–19 vaccine. However, we want to remind SNFs that this measure does not mandate residents be up to date with their COVID–19 vaccine. The number of residents who have been vaccinated in a SNF does not impact a SNF's ability to successfully report the measure to comply with the requirements of the SNF QRP. Finally, we do appreciate SNFs' commitment and efforts at ensuring residents are educated and encouraged to become and

[206] The definition of ''up to date'' may change based on CDC's latest guidelines and can be found on the CDC web page, ''Stay Up to Date with COVID–19 Vaccines Including Boosters,'' at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html* (updated January 9, 2023).

[207] *Patient-Resident-COVID-Vaccine-Draft-Specs.pdf. https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information.*

[208] COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications. *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf.*

[209] Centers for Disease Control and Prevention. Rates of laboratory-confirmed COVID–19 hospitalizations by vaccination status. COVID Data Tracker. 2023, February 9. Last accessed March 22, 2023. *https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination.*

[210] Centers for Disease Control and Prevention. COVID–19 Vaccine Effectiveness Monthly Update. COVID Data Tracker. November 10, 2022. *https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness.*

remain up to date with their COVID–19 vaccinations.

Comment: One commenter noted that, while some SNFs have been extremely successful, especially with their long-stay residents, in having a high degree of acceptance of the COVID–19 vaccines throughout the last 3 years, this success is not a proxy for providing the actual care and services a resident has come to the SNF to receive. Another commenter noted that CMS's statement ''SNFs could choose to administer the vaccine to the resident prior to discharge'' seemed to indicate that vaccination is a SNF's choice, and not a resident's choice.

Response: The primary intent of the Patient/Resident COVID–19 Vaccine measure is to promote transparency of raw data regarding COVID–19 vaccination rates for residents and their caregivers to make informed decisions for selecting facilities. This measure will provide potential residents and their caregivers with an important piece of information regarding vaccination rates as part of their process of identifying SNFs they would want to seek care from, alongside other measures available on Care Compare, to make an informed, comprehensive decision. In response to the comment about our statement in the proposed rule that seemed to indicate vaccination is a SNF's choice, and not a resident's choice, we appreciate the opportunity to clarify the statement. We acknowledge and support a resident's choice about whether to receive an up to date vaccine. Our statement was meant to convey that the SNF could work with the resident to determine the most appropriate approach for them.

Comment: One commenter noted that sometimes patients/residents may not have the opportunity to ''shop'' for a facility outside of their region simply based on the COVID–19 vaccinations rates. They noted that insurance and proximity to loved ones are often the drivers for selecting a post-acute care facility.

Response: We acknowledge that sometimes residents may not have access to as many SNF choices as others. However, we believe that the information provided by this measure will still be valuable to potential SNF residents/caregivers who may have geographic limitations.

Comment: One commenter noted that vaccination administration rates can ebb and flow significantly based on factors outside the control of SNFs, including holidays, weather, vaccine/pharmaceutical supply chain management, staff availability and more.

Response: We are unaware of any access issues to COVID–19 vaccines or vaccine production delays. While we believe SNFs will be able to administer the COVID–19 vaccine if a resident consents, this measure does not require SNFs to administer the vaccine themselves. They could arrange for the resident to obtain the vaccine outside of their facility, or work with community pharmacies to obtain vaccines.

Comment: One commenter agreed with CMS's proposed justification that the measure has the potential to drive COVID–19 vaccination uptake among SNF residents and prevent the spread of COVID–19 in the SNF population and agreed that the measure could help empower consumers in making decisions about their care. Despite this, they still urged CMS to ensure that measures are appropriately specified and adequately tested and validated prior to implementation. This commenter also noted that unlike the proposed HCP COVID–19 Vaccine measure, the specifications for this Patient/Resident COVID–19 Vaccine measure solely reference the definition of up to date as described on CDC's ''Stay Up to Date'' website. Even though this definition more accurately reflects the most current Advisory Committee on Immunization Practices (ACIP) recommendation, the commenter urged CMS to ensure that this approach to specifying measures is valid and will not serve to cause confusion or reporting challenges in the future.

However, several commenters did not support the proposal due to the measure not being fully tested for reliability and validity, and one commenter raised concerns about the feasibility to report this measure as well as the measure's ability to produce statistically meaningful information.

Response: We are pleased that the commenter agrees with our proposed rationale that the measure has the potential to drive COVID–19 vaccination uptake among SNF residents, prevent the spread of COVID–19 in the SNF population, and empower consumers in making decisions about their care.

While we acknowledge that we have not yet tested the measure for reliability and validity, we have tested the item proposed for the MDS to capture data for this measure and its feasibility and appropriateness. Since a COVID–19 vaccination item does not yet exist within the MDS, we developed clinical vignettes to test item-level reliability of a draft Patient/Resident COVID–19 Vaccine measure. The clinical vignettes were a proxy for resident records with the most common and challenging cases SNFs would encounter, similar to the approach that we use to train SNFs on all new assessment items, and the results demonstrated strong agreement (that is, 84 percent).

Validity testing has not yet been completed, since the COVID–19 vaccination item does not yet exist on the MDS. However, the Patient/Resident COVID–19 Vaccine measure was constructed based on prior use of similar items, such as the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) for the IRF and LTCH QRPs.[211] Four Nursing Home Quality Initiative (NHQI) pneumococcal vaccination measures also use similar item construction. We have used these types of patient/resident vaccination assessment items in the calculation of vaccination quality measures in our PAC QRPs and intend to conduct reliability and validity testing for this specific Patient/Resident COVID–19 Vaccine measure once the COVID–19 vaccination item has been added to the MDS and we have collected sufficient data. Additionally, we solicited feedback from our Technical Expert Panel (TEP) on the proposed assessment item and its feasibility. No concerns were raised by the TEP regarding obtaining the information that would be required to complete the new COVID–19 vaccination item.[212]

Comment: Several commenters did not support the measure and pointed to the fact that the MAP Coordinating Committee reached 90 percent consensus on its recommendation of ''do not support with potential for mitigation'' when evaluating this proposed measure. Two of these commenters also urged CMS to delay adoption of the measure until concerns raised by the MAP Coordinating Committee have been addressed. Specifically, they encouraged CMS to address the MAP's recommendations for adding exclusions to the measure, conducting measure testing, and submitting the measure for CBE endorsement. One commenter noted they were deeply concerned about the proposal to adopt the Patient/Resident COVID–19 Vaccine measure because it

[211] 78 FR 47859 and 77 FR 53257.

[212] Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report. *https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf.*

appeared as though CMS disregarded the recommendations of the MAP.

Response: As part of the pre-rulemaking process, HHS takes into consideration the recommendations of the MAP in selecting candidate quality and efficiency measures. HHS selects candidate measures and publishes proposed rules in the **Federal Register**, which allows for public comment and further consideration before a final rule is issued. If the CBE has not endorsed a candidate measure, then HHS must publish a rationale for the use of the measure described in section 1890(b)(7)(B) of the Act in the notice. The MAP Coordinating Committee recommended three mitigation strategies for the Patient/Resident COVID–19 Vaccine measure: (i) reconsider exclusions for medical contraindications, (ii) complete reliability and validity measure testing, and (iii) seek CBE endorsement. We would like to reiterate that this measure is intended to promote transparency of raw data regarding COVID–19 vaccination rates for residents/caregivers to make informed decisions for selecting facilities, providing potential residents with an important piece of information regarding vaccination rates as part of their process of identifying SNFs they would want to seek care from. As we stated in section VI.C.2.a.(3) of the FY 2024 SNF PPS proposed rule, we did not include exclusions for medical contraindications because the PFAs we met with told us that a measure capturing raw vaccination rate, irrespective of any medical contraindications, would be most helpful in resident and family/caregiver decision-making. We intend to conduct measure testing once sufficient data on the COVID–19 vaccination item are collected through the MDS and plan to submit the measure for CBE endorsement when it is technically feasible to do so.

Comment: Several commenters were concerned about the burden this measure places on SNFs as a result of having a new assessment item in the MDS, especially in light of changing guidelines around vaccine requirements, and workforce shortages. One commenter noted that the proposed changes to the measure will require SNFs to track CDC guidance on a quarterly basis and will also require SNFs to change their processes to track whether residents have received multiple doses. Two commenters noted that if CDC were to update its guidance and require booster doses, SNFs would then need to validate and track whether all residents met the new requirements, creating an added burden for SNFs to adapt to the new recommendations that will take both time and staff resources.

Response: To ensure appropriate coding of the assessment item, SNFs would be able to use multiple sources of information to obtain a resident's vaccination status, such as resident interviews, medical records, proxy response, and vaccination cards provided by the resident or their caregivers.[213] As with any assessment item in the MDS, we will also publish coding guidance and instructions to further aid SNFs in collection of these data. Additionally, we believe SNFs should be assessing whether residents are up to date with COVID–19 vaccination as a part of their routine care and infection control processes, and during our item testing, we heard from SNFs that they are routinely inquiring about COVID–19 vaccination status when admitting residents already.

Comment: One commenter was concerned that the proposed Patient/Resident COVID–19 Vaccine measure could have unintended consequences if adopted. Another commenter stated the adoption of the measure would create a difficult dynamic for SNFs. They suggested SNFs would have two choices when making a decision whether to admit a resident who is not up to date with their COVID–19 vaccine: (1) not offer admission to residents who are not up to date with CDC recommendations, because they stated it would result in the SNF receiving a low-quality score on this measure, or (2) admit the resident, administer a COVID–19 vaccination to bring them in line with CDC recommendations even though the vaccine may increase the resident's risk of adverse health outcomes. One commenter pointed to the concerns raised by MAP and other interested parties and states CMS should consider the potential impacts of its approach on vaccination efforts. They caution that as SNFs are endeavoring to follow the vaccine guidelines and gain resident trust, this measure—as constructed—has the potential to adversely impact resident-provider relationships, trust, and provider performance.

Response: We do not anticipate issues with resident access to SNF care if this measure is adopted. Use or adoption of other vaccination measures in PAC settings have not previously impacted access to care. Additionally, SNFs have been required to ''educate and offer'' COVID–19 vaccine to residents, clients, and staff, and report COVID–19 vaccination status to the CDC's NHSN, on a weekly basis, since May 13, 2021.[214] More recently, we finalized certain infection control requirements at § 483.80(d) that SNFs and LTC facilities must meet to participate in the Medicare and Medicaid programs.[215] As finalized in the ''Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) to Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements'' (88 FR 36491 to 36492), SNFs must continue to educate residents, resident representatives, and staff about COVID–19 vaccines and offer a COVID–19 vaccine to residents, resident representatives, and staff, as well as complete the appropriate documentation for these activities. Since the information captured by the Patient/Resident COVID–19 Vaccine measure is consistent with these activities a SNF is already required to perform to meet 42 CFR 483.80(d)(3)(iii) through (vi), we believe SNFs are having those discussions with their residents every day, and the adoption of this measure should not have adverse impacts on resident-provider relationships.

We believe SNFs consider resident care of paramount importance and will not refuse care to residents based on their vaccination status. We also believe SNFs should use clinical judgement to determine if a resident is eligible to receive the vaccination. Lastly, we take the appropriate access to care in SNFs very seriously, and routinely monitor the performance of measures in the SNF QRP, including performance gaps across SNFs. We intend to monitor closely whether any proposed change to the

[213] COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications. *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf.*

[214] Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff (86 FR 26315–26316).

[215] Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements (88 FR 36502).

SNF QRP has unintended consequences on access to care. Should we find any unintended consequences, we will take appropriate steps to address these issues in future rulemaking.

Comment: Several commenters were concerned regarding the lack of a well-defined definition of up to date, and the burden it poses on SNFs to collect these data from residents due to the constantly changing guidelines. One commenter characterized it as a ''moving-target'' definition, and another commenter noted that the CDC maintains different definitions of ''up to date'' and ''fully vaccinated.'' This commenter states that the public has a limited appreciation for the differences in these definitions and could easily misreport their vaccination status to facility staff when asked, giving the public a misleading picture of the vaccination levels of a SNF's resident population. Another commenter noted that it was unclear whether most residents would have an understanding of the CDC's specific definition of ''up to date'' when answering a yes/no question for the resident assessment, leading to potentially inaccurate data.

Response: The concept of up to date is not new and is currently in use by SNFs for the short stay and long stay Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine and Percent of Residents Who Received the Pneumococcal Vaccine measures. Beyond the historical use of this concept, ensuring that standards of care are up to date according to the relevant authorities remains a widespread goal for all SNFs. We believe that SNFs should be staying current on the latest care guidelines of COVID–19 vaccination as part of best practice. Additionally, SNFs would be able to use multiple sources of information available to obtain the vaccination data, such as resident interviews, medical records, proxy response, and vaccination cards provided by the resident or their caregivers. Gathering this information gives the SNF the opportunity to educate residents about what it means to be up to date per CDC guidelines, so that the item can be completed accurately. Further, the MDS Resident Assessment Instrument (RAI) Guidance Manual will indicate how to code the item and SNFs could access the CDC website at any time to find the definition of up to date. The CDC has published FAQs that clearly state the difference in the terms ''fully vaccinated'' and ''up to date.'' [216] Finally, as described in section VII.C.2.b.(1)(b) of this final rule, our item testing demonstrated strong agreement with the correct responses when facilities used the available guidance, and rates increased when facilities accessed the CDC website.

Comment: One commenter noted that given the various lengths of stay for residents, residents may be up to date one month and then with additional boosters and evidence on the horizon, they would move to being not up to date.

Response: Given this assessment item is completed at discharge, SNFs would only code the item using guidance in place at the time of resident discharge.

Comment: One commenter raised concerns about the evolving recommendation landscape from FDA and CDC as well as lack of full authorization from FDA for bivalent vaccines. They stated expert advisory groups will meet in June 2023 to provide additional recommendations to the agencies and to the public and encouraged CMS to delay measure amendment or adoption until future years when greater clarity from experts and other agencies is available. Another commenter was concerned about the uncertainty about the seasonality of COVID–19, future vaccination schedules, and how often new versions of a COVID–19 vaccine will be available.

Response: We disagree with the commenter and do not believe the evolving landscape and recommendations will affect this measure negatively. We recognize that the up to date COVID–19 vaccination definition may evolve due to the changing nature of the virus. As the COVID–19 virus mutates, this vaccination measure takes a forward-thinking approach to ensure that SNF residents are protected in the event of COVID–19 infection. Given that CDC guidelines may change over time in response to the virus, we believe the use of ''up to date'' will actually be simpler for facilities since it ensures that the measure specifications, item responses, and accompanying item guidance would not have to continually change. The public health response to COVID–19 has necessarily adapted to respond to the changing nature of the virus's transmission and community spread. Just as we stated when we finalized the adoption of the HCP COVID–19 Vaccine measure in the FY 2022 SNF PPS final rule (86 FR 42481), we intend to continue to work with partners including FDA and CDC to consider any updates to the Patient/Resident COVID–19 Vaccine measure in future rulemaking as appropriate. We believe that the proposed measure aligns with our responsive approach to COVID–19 and will continue to support vaccination as the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Additionally, FDA recently authorized the bivalent vaccine to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations.[217] Lastly, we regularly review our measures as part of the measure maintenance process and welcome feedback and expert input on our measures, and will re-specify the measure in the future, if needed, based on any changes to guidelines.

Comment: Several commenters did not support the measure due to the lack of exclusions in the measure for reasons such as medical contraindications, religious beliefs, cultural norms, and resident refusals. Some commenters encouraged CMS to consider the MAP's recommendations to add exclusions to the measure calculation. One commenter suggested CMS include a follow-up question to learn why the vaccine is not up to date, like MDS item O0300B for the pneumococcal vaccine, with three response options: ''Not eligible—medical contraindication,'' ''Offered and declined,'' and ''Not offered.''

Response: We thank the commenters for their recommendations about adding exclusions to the measure. Our measure development contractor convened a focus group of PFAs as well as a TEP that included interested parties from every PAC setting, to solicit input on patient/resident COVID–19 vaccination measures and assessment items. The PFAs told us that a measure capturing raw vaccination rates would be most helpful in resident and family/caregiver decision-making. Our TEP agreed that developing a measure to report the rate of vaccination without denominator exclusions was an important goal.[218]

[216] Frequently Asked Questions about COVID–19 Vaccination. May 15, 2023. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.*

[217] Coronavirus (COVID–19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID–19 Vaccines. April 18, 2023. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines.*

[218] Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related

Based on this feedback, we believe excluding patients/residents with contraindications from the measure would distort the intent of the measure of providing raw COVID–19 resident vaccination rates, while making the information more difficult for residents/caregivers to interpret, and hence did not include any exclusions.

Comment: Some commenters did not support adoption of this measure in light of the Administration's announcement of the end of the COVID–19 PHE on May 11, 2023. One of these commenters noted that it will be even more challenging for residents to stay informed on the most recent guidance from the CDC. Another one of these commenters noted that with the end of the PHE and the end of the Federal vaccination mandates, CMS should eliminate any tracking of vaccines. Finally, one of these commenters commended CMS for recognizing the burden of such a requirement included in the SNF Conditions of Participation and working to remove it, but now questions the ''juxtaposition'' of proposing a vaccine uptake measure as a metric for quality of care.

Response: Despite the announcement of the end of the COVID–19 PHE, many people continue to be affected by COVID–19, particularly seniors, people who are immunocompromised, and people with disabilities. As mentioned in the End of COVID–9 Public Health Emergency Fact Sheet,[219] our response to the spread of SARS–CoV–2, the virus that causes COVID–19, remains a public health priority. Even beyond the end of the COVID–19 PHE, we will continue to work to protect Americans from the virus and its worst impacts by supporting access to COVID–19 vaccines, treatments, and tests, including for people without health insurance. Given the continued impacts of COVID–19, we believe it is important to promote resident vaccination and education, which this measure aims to achieve. Accordingly, we are aligning our approach with those for other infectious diseases, such as influenza by encouraging ongoing COVID–19 vaccination.[220] Further, published coding guidance will indicate how to code the item taking into account CDC guidelines, and SNFs could access the CDC website at any time to find the definition of up to date. Lastly, this measure as proposed for the SNF QRP is not associated with the PHE declaration, or the Conditions of Participation. This measure is being proposed to address our priority to empower consumers to make informed health care choices through resident-directed quality measures and public transparency, as with previous vaccination measures.

Comment: One commenter did not support the measure for the SNF QRP because residents entering a Medicare Part A SNF stay have had an acute care stay and they believe the hospital has already determined the person's interest in receiving the COVID–19 vaccine.

Response: We believe that COVID–19 vaccination for high-risk populations, such as those in SNF settings, is of paramount importance. This is particularly important for residents at SNFs, who tend to be older and thus more vulnerable to serious complications from COVID–19. Therefore, if a resident is not vaccinated at the time they are admitted, the SNF has the opportunity to continue to educate the resident and provide information on why they should receive the vaccine, irrespective of whether the resident has received prior education.

Comment: Some commenters provided alternate recommendations for a measure of a SNF's action, such as a count of the number of documented encounters facility staff had with a resident and/or their family concerning the COVID–19 vaccine, or a process measure that collects data on vaccines that are offered to residents in SNFs that are eligible for boosters. One commenter recommended a ''balancing measure'' which would track whether a SNF recommended the resident become up to date with their COVID–19 vaccine as opposed to tracking whether the resident accepted and received a COVID–19 vaccine.

Response: We appreciate the input from the commenters. We did not propose a measure of SNF action related to the measure but will use this input to inform our future measure development efforts.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Patient/Resident COVID–19 Vaccine measure as an assessment-based measure beginning with the FY 2026 SNF QRP as proposed.

D. Principles for Selecting and Prioritizing SNF QRP Quality Measures and Concepts Under Consideration for Future Years—Request for Information (RFI)

1. Solicitation of Comments

We solicited general comments on the principles for identifying SNF QRP measures, as well as additional thoughts about measurement gaps, and suitable measures for filling these gaps. Specifically, we solicited comment on the following questions:

- Principles for Selecting and Prioritizing QRP Measures

++ To what extent do you agree with the principles for selecting and prioritizing measures?

++ Are there principles that you believe CMS should eliminate from the measure selection criteria?

++ Are there principles that you believe CMS should add to the measure selection criteria?

- SNF QRP Measurement Gaps

++ We requested input on the identified measurement gaps, including in the areas of cognitive function, behavioral and mental health, resident experience and resident satisfaction, chronic conditions and pain management.

++ Are there gaps in the SNF QRP measures that have not been identified in this RFI?

- Measures and Measure Concepts Recommended for Use in the SNF QRP.

++ Are there measures that you believe are either currently available for use, or that could be adapted or developed for use in the SNF QRP program to assess performance in the areas of (1) cognitive functioning, (2) behavioral and mental health, (3) resident experience and resident satisfaction, (4) chronic conditions, (5) pain management, or (6) other areas not mentioned in this RFI?

We also sought input on data available to develop measures, approaches for data collection, perceived challenges or barriers, and approaches for addressing challenges. We received several comments in response to this RFI, which are summarized below.

Comments on Principles for Selecting and Prioritizing QRP Measures: Many commenters expressed support for the measure selection and prioritization criteria identified by CMS in the FY 2024 SNF PPS proposed rule (88 FR

Items and Measures Summary Report. *https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf.*

[219] Fact Sheet: End of the COVID–19 Public Health Emergency. U.S. Department of Health and Human Services. May 9, 2023. *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html.*

[220] Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements. (88 FR 36487).

21353), as well as those espoused through the National Quality Strategy and the ''Universal Foundation'' of quality measures. In addition to support for these principles, commenters emphasized the importance of prioritizing measures that are meaningful to residents and their caregivers; support shared decision-making; promote continuity or consistency across a range of accountability programs; are constructed from data that are clearly defined, validated, and standardized; for which the SNF is able to influence outcomes; and are consensus-based.

A couple of commenters expressed appreciation for CMS' interest in adopting quality measures that do not impose undue administrative or financial burden on SNFs. These commenters urged that, when considering whether to adopt a measure, CMS assess SNF (including rural SNF) costs in terms of time, money, and staff resources.

Many commenters suggested principles that relate to the types of data that are used in measure construction. For instance, one commenter recommended that measures that are incorporated into the SNF QRP emphasize resident-reported outcomes. Other commenters recommended that measures not be based on facility self-reported data, such as the MDS, due to concerns about data accuracy and completeness. Some commenters recommended that CMS focus on data sources considered to be more objective, such as claims-based measures, the Payroll Based Journal (PBJ), and State surveys. One commenter emphasized the importance of ensuring that regardless of the assessment tool used, requirements for staff training, certification, and interim certification are met.

Comments on Principles for Selecting and Prioritizing QRP Measures and Measures and Measure Concepts Recommended for Use in the SNF QRP: Several commenters agreed with CMS that SNF QRP measurement gaps exist in domains that include cognitive function, behavioral and mental health, resident experiences of care and satisfaction, and chronic condition and pain management.

Cognitive Function

Although several commenters noted the importance of developing quality measures that focus on cognitive function, one commenter suggested caution in selecting measures of cognitive functioning. According to this commenter, SNFs have limited ability to meaningfully influence cognitive functioning during a typical SNF stay.

One commenter indicated that despite the usefulness of a cognitive function measure, the MDS is one of the only available data sources to develop this measure which, according to the commenter, is neither reliable nor accurate.

A few commenters voiced concerns about the use of the BIMS and CAM© in measure development. Some commenters indicated that the BIMS, for example, was designed to screen for the presence of cognitive impairment and determine residents' need for further cognitive assessment. Commenters noted that the BIMS was not intended to diagnose or track changes in cognition; and it only effectively assesses basic elements of cognition (for example, attention, short-term memory), rather than executive functioning, judgment, and other higher-level cognitive functions. One commenter also stated that the constructs that are measured by the BIMS are not those that are the typical focus of therapy.

Other concerns about the BIMS or CAM© for use in development of measures of cognitive functioning included the lack of physician buy-in, variation in the reliability of scoring, and limited utility of the BIMS for measuring and risk adjusting resident cognition and communication.

A commenter indicated that instruments identified in the FY 2024 SNF PPS proposed rule (88 FR 21353 to 21354) RFI (for example, PROMIS Cognitive Function Short Form) are not utilized by many SNFs. Because therapy practitioners are more familiar with the BIMS and CAM© than with other cognitive function instruments mentioned in the RFI—the PROMIS short forms and the PROMIS Neuro-QoL—the commenter thought that use of PROMIS measures would present a greater burden to SNFs. This commenter further indicated that the PROMIS tools were developed for use in broad populations or to measure specific cognitive functions and, as such, would not readily translate to a SNF QRP measure. The commenter recommended that CMS perform feasibility, reliability, and validity testing to ensure that QRP measures could be effectively developed from these instruments.

Commenters encouraged CMS to collaborate with SNFs and experts in cognition to assess and consider other measures that not only offer information on a broad set of elements related to cognitive function but could also be used to assess change in cognitive abilities throughout the course of the SNF episode. One commenter indicated that the proprietary nature of many instruments that assess cognitive functioning could be a challenge for measure development.

Behavioral and Mental Health

A few commenters agreed with CMS that measurement gaps exist in the areas of behavioral and mental health. One commenter indicated that although a measure of behavioral and mental health would be useful, the MDS is one of the only available data sources that could be used to develop this measure. The commenter questioned the accuracy and reliability of the MDS.

One commenter noted that because occupational therapists have a key role in addressing residents' behavioral and mental health needs, that they need to be included in quality measures in this area. Another commenter suggested caution in selecting measures of behavioral and mental health functioning, indicating that SNFs are not specialized in treating behavioral and mental health issues.

Resident Experience and Resident Satisfaction

One commenter expressed support for the use of the CAHPS measure to measure resident experience and satisfaction but cautioned that an independent contractor should be used to identify the resident sample—rather than having SNFs identify this sample—and CMS should ensure that the survey sample mirrors the SNF population using a random sample process.

Chronic Condition and Pain Management

One commenter acknowledged the importance of measures of chronic condition and pain management. However, they did not support development of measures in this area as they believed the MDS to be inaccurate and subject to gaming by nursing facilities.

Other Measurement Gaps

Some commenters believed measurement gaps do exist in domains not identified in the RFI. Noting the importance of good nutrition in reducing readmissions and increasing SNF resident quality of life, two commenters recommended the inclusion of a malnutrition screening and intervention measures in the SNF QRP to promote both quality and health equity. These commenters suggested that malnutrition-related quality measures that CMS has adopted in other quality programs be considered as the foundation for a SNF QRP malnutrition measure. These include the Global

Composite Malnutrition Score which will be used in the Hospital Inpatient Quality Reporting program beginning in 2024, and the Food Insecurity/Nutrition Risk Identification and Treatment Improvement Activity that is part of the Merit-based Incentive Payment System.

Another commenter recommended the adoption of structural measures that indicate hours of service provided by physicians, social workers, and therapists to ensure that residents receive needed services. The commenter supported the use of data from the CMS PBJ to develop these measures.

Commenters expressed support for the development of measures focused on degenerative cognitive conditions, for which maintenance of function is the primary focus. One commenter suggested consideration of a measure related to residents' ability to safely and effectively return to the community.

Other measures and measurement concepts identified by commenters include health equity, psychosocial issues, caregiver status (for example, availability of caregiver), receipt of or referral for smoking cessation counseling among residents with COPD, referrals to pulmonary rehabilitation for residents with COPD, and resident vaccination status, including adult Td/Tdap (tetanus, diphtheria, and pertussis) and herpes zoster (shingles) vaccinations.

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this input to inform our future measure development efforts.

E. Health Equity Update

1. Background

In the FY 2023 SNF PPS proposed rule (87 FR 22754 through 22760), we included an RFI entitled ''Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs.'' We define health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [221] We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs and models, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive. Our goals outlined in the *CMS Framework for Health Equity 2022–2023* [222] are in line with Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.'' [223] The goals included in the CMS Framework for Health Equity serve to further advance health equity, expand coverage, and improve health outcomes for the more than 170 million individuals supported by our programs, and set a foundation and priorities for our work, including: strengthening our infrastructure for assessment; creating synergies across the healthcare system to drive structural change; and identifying and working to eliminate barriers to CMS-supported benefits, services, and coverage. The CMS Framework for Health Equity outlines the approach CMS will use to promote health equity for enrollees, mitigate health disparities, and prioritize CMS's commitment to expanding the collection, reporting, and analysis of standardized data.[224]

In addition to the CMS Framework for Health Equity, we seek to advance health equity and whole-person care as one of eight goals comprising the CMS National Quality Strategy (NQS).[225] The NQS identifies a wide range of potential quality levers that can support our advancement of equity, including: (1) establishing a standardized approach for resident-reported data and stratification; (2) employing quality and value-based programs to address closing equity gaps; and (3) developing equity-focused data collections, analysis, regulations, oversight strategies, and quality improvement initiatives.

A goal of the NQS is to address persistent disparities that underlie our healthcare system. Racial disparities in health, in particular, are estimated to cost the U.S. $93 billion in excess medical costs and $42 billion in lost productivity per year, in addition to economic losses due to premature deaths.[226] At the same time, racial and ethnic diversity has increased in recent years with an increase in the percentage of people who identify as two or more races accounting for most of the change, rising from 2.9 percent to 10.2 percent between 2010 and 2020.[227] Therefore, we need to consider ways to reduce disparities, achieve equity, and support our diverse beneficiary population through the way we measure quality and display the data.

We solicited public comments via the aforementioned RFI on changes that we should consider in order to advance health equity. We refer readers to the FY 2023 SNF PPS final rule (87 FR 47553 through 47555) for a summary of the public comments and suggestions we received in response to the health equity RFI. In the proposed rule, we stated that we would take these comments into account as we continue to work to develop policies, quality measures, and measurement strategies on this important topic.

2. Anticipated Future State

We are committed to developing approaches to meaningfully incorporate the advancement of health equity into the SNF QRP. One option we are considering is including social determinants of health (SDOH) as part of new quality measures.

Social determinants of health are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. They may have a stronger influence on the population's health and well-being than services delivered by practitioners and healthcare delivery organizations.[228] Measure stratification by CMS is important for better understanding differences in health outcomes from across different patient population groups according to specific demographic and SDOH variables. For example, when ''pediatric measures

[221] Centers for Medicare & Medicaid Services. Health Equity. *https://www.cms.gov/pillar/health-equity.* Accessed February 1, 2023.

[222] Centers for Medicare & Medicaid Services. CMS Framework for Health Equity 2022–2032. *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[223] Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' can be found at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[224] Centers for Medicare and Medicaid Services. The Path Forward: Improving Data to Advance Health Equity Solutions. *https://www.cms.gov/files/document/path-forwardhe-data-paper.pdf.*

[225] Centers for Medicare & Medicaid Services. What Is the CMS Quality Strategy? *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[226] Turner A. The Business Case for Racial Equity: A Strategy for Growth. April 24, 2018. W.K. Kellogg Foundation and Altarum. *https://altarum.org/RacialEquity2018.*

[227] World Health Organization. Social Determinants of Health. *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.*

[228] Agency for Healthcare Research and Quality. 2022 National Healthcare Quality and Disparities Report. November 2022. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

over the past two decades are stratified by race, ethnicity, and income, they show that outcomes for children in the lowest income households and for Black and Hispanic children have improved faster than outcomes for children in the highest income households or for White children, thus narrowing an important health disparity.'' [229] This analysis and comparison of the SDOH items in the assessment instruments support our desire to understand the benefits of measure stratification. Hospital providers receive such information in their confidential feedback reports, and we believe this learning opportunity would benefit PAC providers. The goal of the confidential feedback reports is to provide SNFs with their results so they can compare certain quality measures stratified by dual eligible status and race and ethnicity. The process is meant to increase provider's awareness of their data. We will solicit feedback from SNFs for future enhancements to the confidential feedback reports.

In the proposed rule, we stated that we are considering whether health equity measures we have adopted for other settings,[230] such as hospitals, could be adopted in PAC settings. We stated that we are exploring ways to incorporate SDOH elements into the measure specifications. For example, we could consider a future health equity measure like screening for social needs and interventions using our current SDOH Data items of preferred language, interpreter services, health literacy, transportation, and social isolation. With 30 percent to 55 percent of health outcomes attributed to SDOH,[231] a measure capturing and addressing SDOH could encourage SNFs to identify residents' specific needs and connect them with the community resources necessary to overcome social barriers to their wellness. We could specify a health equity measure using the same SDOH data items that we currently collect as standardized patient assessment data elements under the SNF. These SDOH data items assess health literacy, social isolation, transportation problems, and preferred language (including need or want of an interpreter). We also see value in aligning SDOH data items according to existing health IT vocabulary and codes sets where applicable and appropriate such as those included in the Office of the National Coordinator for Health Information (ONC) United States Core Data for Interoperability (USCDI) [232] across all care settings as we develop future health equity quality measures under our SNF QRP statutory authority. This would further the goals of the NQS to align quality measures across our programs as part of the Universal Foundation.[233]

Although we did not directly solicit feedback to our update, we did receive some public comments, which we summarize later in this section.

Comment: Commenters were generally supportive of CMS' efforts to develop ways to measure and mitigate health inequities. Four commenters applauded CMS' continuing efforts to advance health equity and encouraged CMS to continue to develop and adopt measures of SDOH into the SNF QRP. One of these commenters referenced their belief that collection of SDOH will enhance holistic care, call attention to impairments that might be mitigated or resolved, and facilitate clear communication between residents and SNFs. Another commenter shared strategies they are using with their member organizations to assess organizational leadership's commitment to identify and address health equity, as well as evaluating the impact of health equity on care delivery.

We also received comments supporting measure stratification and adoption of screening measures in the SNF QRP. One commenter noted the importance of stratification to understanding the differences in outcomes across different groups. Some commenters suggested CMS incorporate screening measures similar to those adopted in the FY 2023 Inpatient Prospective Payment System (IPPS) final rule for the Hospital Inpatient Quality Reporting Program.

We also received feedback on other ways to incorporate health equity into the SNF QRP. One commenter recommended CMS incorporate workforce equity measures into the SNF QRP, suggesting that workforce factors are related to a worker's ability to provide quality care. We received some comments on other data points that may be useful in identifying and addressing health disparities. One commenter noted that while it is important to still try to understand differences by race and ethnicity to identify and address disparities that might root from racism and social/economic inequities, they recommended against making generalizations about differences in health and health care simply based on race and ethnicity and to instead conduct more in-depth evaluations of underlying social and economic drivers of health. This commenter suggested CMS incentivize the collection and analysis of data on factors such as, but not limited to, disability status, veteran status, primary or preferred language, health literacy, food security, transportation access, housing stability, social support after discharge from a SNF, and a person's access to care. This same commenter, however, pointed out that any program must account for the fact that there are many contributors to health inequities, including personal factors, many of which are outside the control of SNFs. They encouraged CMS to have ongoing engagement from interested parties to best understand structural and socioeconomic barriers to health and to monitor for any unintended consequences. Finally, this commenter urged CMS to focus on improving care coordination as residents move between settings.

One commenter recommended CMS consider including SDOH in new quality measures and in SNF payment and suggested it could be accomplished through the use of ICD–10 Z-codes as indicators of the additional resources required to care for residents. There were also several commenters who urged CMS to balance any reporting requirements so as not to create an undue administrative burden on clinicians. One of these commenters noted that quantifying health care disparities and barriers faced by residents is extremely nuanced due to the sensitive nature of this issue, and an overly burdensome reporting approach may impact the critical relationship between the SNF and resident.

One commenter was critical of our efforts to meaningfully incorporate the advancement of health equity into the SNF QRP, noting that it disregards a person's behavior and accountability for their own health. This commenter raised a concern that these efforts presuppose systemic bias on the part of

[229] Agency for Healthcare Research and Quality. 2022 National Healthcare Quality and Disparities Report. Content last reviewed November 2022. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

[230] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation. (87 FR 49202–49215).

[231] World Health Organization. Social Determinants of Health. *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.*

[232] United States Core Data for Interoperability (USCDI), *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[233] Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS—The Universal Foundation. N Engl J Med. 2023 Mar 2;338:776–779. doi: 10.1056/NEJMp2215539. PMID: 36724323.

the healthcare system or bigotry on the part of medical providers, or that medical providers' bias is responsible for differences in the health outcomes among demographic minority groups. This commenter also cautioned CMS against expecting providers to view treatments through the lens of race, as it could result in allocating resources to one group at the expense of another.

Finally, one commenter suggested that the abbreviated term for ''social determinants of health'' was incorrect, believing it should be SDoH.

Response: We thank all the commenters for responding to our update on this important CMS priority. When abbreviating ''social determinants of health,'' we consistently use SDOH across our agencies and programs.[234] [235] [236] [237] [238] We also want to be transparent about our efforts to provide SNFs with information that they find beneficial as they seek to improve clinical outcomes for all SNF residents and are not intended to be critical of any health system or provider. As we stated in the FY 2024 SNF PPS proposed rule (88 FR 21355–21356), our goals outlined in the *CMS Framework for Health Equity 2022–2023* [239] are in line with Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.'' [240] We will continue to prioritize our efforts to advance health equity by designing, implementing, and operationalizing policies and programs that support health for *all* people served by our program. As we move this important work forward, we will take these comments into account as we work to develop policies, quality measures, and measurement strategies.

F. Form, Manner, and Timing of Data Submission Under the SNF QRP

1. Background

We refer readers to the current regulatory text at § 413.360(b) for information regarding the policies for reporting SNF QRP data.

2. Reporting Schedule for the Minimum Data Set (MDS) Assessment Data for the Discharge Function Score Measure Beginning With the FY 2025 SNF QRP

As discussed in section VI.C.1.b. of the FY 2024 SNF PPS proposed rule, we proposed to adopt the DC Function measure beginning with the FY 2025 SNF QRP. We proposed that SNFs would be required to report these MDS assessment data beginning with residents admitted and discharged on October 1, 2023 for purposes of the FY 2025 SNF QRP. Starting in CY 2024, SNFs would be required to submit data for the entire calendar year beginning with the FY 2026 SNF QRP. Because the DC Function measure is calculated based on data that are currently submitted to the Medicare program, there would be no new burden associated with data collection for this measure.

We solicited public comment on this proposal. We did not receive public comments on this proposed schedule for data submission of the DC Function measure beginning with the FY 2025 SNF QRP, and therefore, we are finalizing as proposed.

3. Method of Data Submission and Reporting Schedule for the CoreQ: Short Stay Discharge Measure Beginning With the FY 2026 SNF QRP

a. Method of Data Submission To Meet SNF QRP Requirements Beginning With the FY 2026 Program Year

As discussed in section VII.C.2.a. of this final rule, we proposed to adopt the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP. In the FY 2024 SNF PPS proposed rule (88 FR 21357), we proposed that Medicare-certified SNFs and all non-CAH swing bed rural hospitals would be required to contract with a third-party vendor that is CMS-trained and approved to administer the CoreQ: SS DC survey on their behalf (referred to as a ''CMS-approved CoreQ survey vendor''). Under this proposal, SNFs would have been required to contract with a CMS-approved CoreQ survey vendor to ensure that the data are collected by an independent organization that is trained to collect this type of data and given the independence of the CMS-approved CoreQ survey vendor from the SNF, ensure that the data collected are unbiased. The CMS-approved CoreQ survey vendor would have been the business associate of the SNF and required to follow the minimum business requirements described in the Draft CoreQ: SS DC Survey Protocols and Guidelines Manual.[241] This method of data collection has been used successfully in other settings, including for Medicare-certified home health agencies and hospices.

As described in the FY 2024 SNF PPS proposed rule (88 FR 21357), it was proposed that CMS-approved CoreQ survey vendors administering the CoreQ: SS DC survey would be required to offer a toll-free assistance line and an electronic mail address which respondents could use to seek help.

We also proposed in the FY 2024 SNF PPS proposed rule (88 FR 21357) to require SNFs to use the protocols and guidelines for the proposed CoreQ: SS DC measure as defined by the Draft CoreQ: SS Survey Protocols and Guidelines Manual in effect at the time the questionnaires are sent to eligible residents. The Draft CoreQ: SS DC Survey Protocols and Guidelines Manual is available on the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information.* We also proposed that CMS-approved CoreQ survey vendors and SNFs be required to participate in CoreQ: SS DC measure oversight activities to ensure compliance with the protocols, guidelines, and questionnaire requirements. Additionally, we proposed that all CMS-approved CoreQ survey vendors develop a Quality Assurance Plan (QAP) for CoreQ: SS DC survey administration in accordance with the Draft CoreQ: SS DC Survey Protocols and Guidelines Manual.

At § 413.360, we also proposed redesignating paragraph (b)(2) as paragraph (b)(3) and add new paragraph (b)(2) for the CoreQ: SS DC measure's data submission requirements. Finally,

[234] Centers for Disease Control and Prevention. Social Determinants of Health at CDC. *https://www.cdc.gov/about/sdoh/index.html.*

[235] Office of the Assistant Secretary for Health. Social Determinants of Health. *https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[236] National Institutes of Health. PhenX Social Determinants of Health Assessments Collection. *https://www.nimhd.nih.gov/resources/phenx/.*

[237] Office of Minority Health. Using Z Codes: The Social Determinants of Health (SDOH) Data Journey to Better Outcomes. *https://www.cms.gov/files/document/zcodes-infographic.pdf.*

[238] Assistant Secretary for Planning and Evaluation. Addressing Social Determinants of Health in Federal Programs. *https://aspe.hhs.gov/topics/health-health-care/social-drivers-health/addressing-social-determinants-health-federal-programs.*

[239] Centers for Medicare & Medicaid Services. CMS Framework for Health Equity 2022–2032. April 2022. *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[240] Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.'' *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[241] Draft CoreQ: SS DC Survey Protocols and Guidelines Manual. Chapter III. CoreQ Survey Participation Requirements. Available on the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information.*

we proposed to codify the requirements for being a CMS-approved CoreQ: SS DC survey vendor at paragraphs (b)(2)(ii) through (b)(2)(iii) in regulation. The proposed revisions are outlined in the FY 2024 SNF PPS proposed rule (88 FR 21422).

In the FY 2024 SNF PPS proposed rule (88 FR 21358), we proposed that SNFs would send a resident information file (RIF) to the CMS-approved CoreQ survey vendor on a weekly basis so the vendor can start administering the CoreQ: SS DC questionnaire within seven days after the reporting week closes. However, we received a significant number of comments expressing concern about the burden associated with weekly data submission.

We solicited public comment on this proposal to require Medicare-certified SNFs to contract with a third-party vendor to administer the CoreQ: SS DC measure questionnaire on their behalf beginning with the FY 2026 SNF QRP. We received comments that supported and opposed our proposal to require Medicare-certified SNFs to contract with a third-party vendor to administer the CoreQ: SS DC measure questionnaire on their behalf, but we will not be responding to these. As described in section VII.C.2.a.5.b of this final rule, we have decided that, at this time, we will not finalize the proposal to add the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP. Therefore, we are not finalizing our proposal to require Medicare-certified SNFs to contract with a third-party vendor to administer the CoreQ: SS DC measure questionnaire on their behalf beginning with the FY 2026 SNF QRP.

b. Exemptions for the CoreQ: SS DC Measure Reporting Requirements Beginning With the FY 2026 Program Year

(1) Low Volume Exemptions

We are aware that there is a wide variation in the size of Medicare-certified SNFs. Therefore, we proposed that SNFs with less than 60 residents, regardless of payer, discharged within 100 days of SNF admission in the prior calendar year would be exempt from the CoreQ: SS DC measure data collection and reporting requirements. A SNF's total number of short-stay discharged residents for the period of January 1 through December 31 for a given year would have been used to determine if the SNF would have to participate in the CoreQ: SS DC measure in the next calendar year. To qualify for the exemptions, SNFs would have been required to submit their request using the Participation Exemption Request form no later than December 31 of the CY prior to the reporting CY.

(2) New Provider Exemptions

We also proposed in the FY 2024 SNF PPS proposed rule (88 FR 21357 through 21358), that newly Medicare-certified SNFs (that is, those certified on or after January 1, 2024) be excluded from the CoreQ: SS DC measure reporting requirement for CY 2024, because there would be no information from the previous CY to determine whether the SNF would be required to report or exempt from reporting the CoreQ: SS DC measure.

In future years, we proposed requiring that SNFs certified for Medicare participation on or after January 1 of the reporting year would be excluded from reporting on the CoreQ: SS DC measure for the applicable SNF QRP program year.

We solicited public comment on this proposal to exempt SNFs with less than 60 residents, regardless of payer, discharged within 100 days of SNF admission in the prior calendar year, and to exempt newly Medicare-certified SNFs in their first-year of certification, from the CoreQ: SS DC measure reporting requirements for the applicable SNF QRP program year.

We received comments that supported and opposed our proposal to exempt SNFs with less than 60 residents, regardless of payer, discharged within 100 days of SNF admission in the prior calendar year, and to exempt newly Medicare-certified SNFs in their first year of certification from the CoreQ: SS DC measure reporting requirements for the applicable SNF QRP program year, but we will not be responding to these. As described in section VII.C.2.a.5.b of this final rule, we have decided that, at this time, we will not finalize the proposal to add the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP. Therefore, we are not finalizing our proposal to exempt SNFs with less than 60 residents, regardless of payer, discharged within 100 days of SNF admission in the prior calendar year, and to exempt newly Medicare-certified SNFs in their first year of certification from the CoreQ: SS DC measure reporting requirements for the applicable SNF QRP program year.

c. Reporting Schedule for the Data Submission of the CoreQ: Short Stay Discharge Measure Beginning With the FY 2026 SNF QRP

In the FY 2024 SNF PPS proposed rule (88 FR 21358 through 21360), we proposed that the CoreQ: SS DC measure questionnaire be a component of the SNF QRP for the FY 2026 SNF QRP and subsequent years. To comply with the SNF QRP reporting requirements for the FY 2026 SNF QRP, we proposed that SNFs would be required to collect data for the CoreQ: SS DC measure by utilizing CMS-approved CoreQ survey vendors in compliance with the proposed revisions outlined at § 413.360(b)(2)(i) through (b)(2)(iii) in the regulation text of the FY 2024 SNF PPS proposed rule.

For the CoreQ: SS DC measure, we proposed that SNFs would send a resident information file to the CMS-approved CoreQ survey vendor on a weekly basis so the CMS-approved CoreQ survey vendor could start administering the CoreQ: SS DC questionnaire within 7 days after the reporting week closes. The resident information file, whose data is listed in Table 14, represented the minimum required information the CMS-approved CoreQ survey vendor would need to determine the residents' eligibility for the CoreQ: SS DC measure's questionnaire to administer the survey to eligible residents.

TABLE 14—DATA ELEMENTS IN THE COREQ: SS DC MEASURE RESIDENT INFORMATION FILE

SNF name.
SNF CMS Certification Number (CCN).
National Provider Identifier (NPI).
Reporting week.
Reporting year.
Number of eligible residents.
Resident First Name.
Resident Middle Initial.
Resident Last Name.
Resident Date of Birth.
Resident Mailing Address 1.
Resident Mailing Address 2.
Resident address, City.
Resident address, State.
Resident address, Zip Code.
Telephone number, including area code.
Resident email address.
Gender.
Payer.
HMO indicator.
Dual eligibility indicator.
End stage renal disease.
Resident date of admission.
Resident date of discharge.
Brief Interview for Mental Status (BIMS) score.
Discharge status.
Left against medical advice.
Court appointed guardian.
Are you of Hispanic, Latino/a, or Spanish origin?
What is your race?

TABLE 14—DATA ELEMENTS IN THE COREQ: SS DC MEASURE RESIDENT INFORMATION FILE—Continued

What is your preferred language?
For additional information about the data elements that would be included in the resident information file, see the Draft CoreQ Protocols and Guidelines Manual located at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information*.

For the CoreQ: SS DC measure, we proposed that SNFs would be required to meet or exceed two separate data completeness thresholds: (1) one threshold, set at 75 percent, for submission of weekly resident information files to the CMS-approved CoreQ survey vendor for the full reporting year; and (2) a second threshold, set at 90 percent, for completeness of the resident information files. In other words, as proposed, SNFs would have submitted resident information files on a weekly basis that included at least 90 percent of the required data fields to their CMS-approved CoreQ survey vendors for at least 75 percent of the weeks in a reporting year. SNFs could have chosen to submit resident information files more frequently but would have been required meet the minimum threshold to avoid receiving a 2-percentage-point reduction to their Annual Payment Update (APU). We also proposed to codify this data completeness threshold requirement at our regulation at § 413.360(f)(1)(iv) as described in the regulation text of the FY 2024 SNF PPS proposed rule.

We also proposed an initial data submission period from January 1, 2024, through June 30, 2024. As described in Table 15 in the FY 2024 SNF PPS proposed rule (88 FR 21359), we proposed that to meet the pay-for-reporting requirement of the SNF QRP for the first half of the FY 2026 program year, SNFs would only be required to contract with a CMS-approved CoreQ survey vendor and submit one resident information file to their CMS-approved CoreQ survey vendor for at least 1 week during January 1, 2024 through June 30, 2024. During this period, the CMS-approved CoreQ survey vendor would follow the procedures as described in the Draft CoreQ: SS DC Survey Protocols and Guidelines Manual.[242] Beginning July 1, 2024, SNFs would have been required to submit weekly resident information files for at least 75 percent of the weeks remaining in CY 2024.

Starting in CY 2025, SNFs would be required to submit resident information files no less than weekly for the entire calendar year beginning with the FY 2027 SNF QRP, as described in Table 16 in the FY 2024 SNF PPS proposed rule (88 FR 21359).

We proposed that the CMS-approved CoreQ survey vendor administer the CoreQ: SS DC measure's questionnaire to discharged residents within 2 weeks of their discharge date through the U.S. Postal Service or by telephone. If administered by mail, the questionnaires must be returned to the CMS-approved CoreQ survey vendor within 2 months of the resident's discharge date from the SNF.

Although the CMS-approved CoreQ survey vendor would administer the CoreQ: SS DC measure's survey on a SNF's behalf, each SNF would have been responsible for ensuring required data are collected and submitted to CMS in accordance with the SNF QRP's requirements. We also recommended that SNFs submitting CoreQ: SS DC resident information files to their CMS-approved CoreQ survey vendor promptly review the Data Submission Summary Reports that are described in the Draft CoreQ: SS DC Survey Protocols and Guidelines Manual.[243]

We solicited public comment on the proposed schedule for data submission and the participation requirements for the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP. We received several comments on our proposed schedule for data submission and the participation requirements for the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP, but we will not be responding to these. As described in section VII.C.2.a.5.b of this final rule, we have decided that, at this time, we will not finalize the proposal to add the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP. Therefore, we are not finalizing our proposed schedule for data submission and the participation requirements for the CoreQ: SS DC Measure beginning with the FY 2026 SNF QRP.

4. Reporting Schedule for the Data Submission of Minimum Data Set (MDS) Assessment Data for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2026 SNF QRP

As discussed in section VI.C.2.b. of the FY 2024 SNF PPS proposed rule, we proposed to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 SNF QRP. We proposed that SNFs would be required to report this new MDS assessment data item beginning with Medicare Part A residents discharged on October 1, 2024, for purposes of the FY 2026 SNF QRP. Starting in CY 2025, SNFs would be required to submit data for the entire calendar year beginning with the FY 2027 SNF QRP.

We also proposed to add a new item to the MDS for SNFs to report the proposed Patient/Resident COVID–19 Vaccine measure. Specifically, a new item would be added to the MDS discharge item sets to collect information on whether a resident is up to date with their COVID–19 vaccine at the time of discharge from the SNF. A draft of the new item is available in the *COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date* Draft Measure Specifications.[244]

We solicited public comment on this proposal. The following is a summary of the comments we received on our proposal to require SNFs to report a new MDS assessment data item for the Patient/Resident COVID–19 Vaccine measure on Medicare Part A residents beginning with residents discharged on October 1, 2024 and our responses.

Comment: Several commenters raised concerns about the data collected using the assessment item on the MDS being duplicative of what is currently being reported to NHSN. They noted that this reporting adds additional burden on SNFs and could confuse residents looking for information. One commenter recommended that in order to remove burdensome duplication of reporting for the same process, CMS should issue a regulatory revision to the requirements promulgated through a prior COVID–19 IFC[245] to end reporting of resident COVID–19 vaccination up to date status

[242] Draft CoreQ: SS DC Survey Protocols and Guidelines Manual. Available on the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information*.

[243] Draft CoreQ: SS DC Survey Protocols and Guidelines Manual. Chapter X. SNF CoreQ Survey website Reports. Available on the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information*.

[244] *COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date* Draft Measure Specifications. *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf*.

[245] Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff (86 FR 26315–26316).

requirements through the NHSN no later than September 30, 2024.

Response: We acknowledge the commenters' concerns and thank them for their recommendations regarding the duplication of reporting resident COVID–19 vaccination status on the MDS and to NHSN. We will take the recommendations into consideration.

Comment: Some commenters noted their preference for the NHSN reported data, since it includes the entire nursing home population regardless of payer source and provides more valuable information, as opposed to this proposed SNF QRP measure which only reflects short-stay residents.

Response: While the data that SNFs report to the NHSN are aggregated resident vaccination data, SNF's are not required to report beneficiary-level data to the CDC's NHSN. However, since the proposed Patient/Resident COVID–19 Vaccine measure would be collected using an MDS assessment item at the resident-level, the data submitted would be included in the SNF's Review and Correct reports as well as the Quality Measure (QM) resident- and facility-level confidential feedback reports and would allow SNFs to track resident-level information for quality improvement purposes. These data would also allow for granular analyses of vaccinations, including identification of potential disparities within the SNF QRP.

Comment: A few commenters raised concerns about this measure being based on facility self-reported MDS data and its reliability. Commenters urged CMS to consider alternative data sources or implement auditing and penalty systems for inaccurate or falsified data, if an MDS assessment item was finalized as the source to collect this information. One commenter suggested that having a single yes or no item on the MDS without any requirements for documentation or validation of vaccination status would amount to a mere checkmark in a box with no evidence that it leads to improved quality of care.

Response: We acknowledge the commenters' concerns regarding the MDS data. However we note that the RAI process has multiple regulatory requirements. Our regulations at §§ 483.20(b)(1)(xviii), (g), and (h) [246] require that (1) the assessment must be a comprehensive, accurate assessment of the resident's status, (2) the assessment must accurately reflect the resident's status, (3) a registered nurse and each individual who completes a portion of the assessment must sign and certify the assessment is completed, and (4) the assessment process includes direct observation, as well as communication with the resident.

We intend to monitor this measure closely to identify any concerning trends, and we will continue to do so as part of our routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the SNF QRP.

After consideration of the public comments we received, we are finalizing our proposal to require SNFs to report the new MDS assessment data item for the Patient/Resident COVID–19 Vaccine measure on Medicare Part A residents beginning with residents discharged on October 1, 2024 for the FY 2026 SNF QRP.

5. SNF QRP Data Completion Thresholds for MDS Data Items Beginning With the FY 2026 SNF QRP

In the FY 2016 SNF PPS final rule (80 FR 46458), we finalized that SNFs would need to complete 100 percent of the data on 80 percent of MDSs submitted in order to be in compliance with the SNF QRP reporting requirements for the applicable program year, as codified in regulation at § 413.360(f). We established this data completion threshold because SNFs were accustomed to submitting MDS assessments for other purposes and they should easily be able to meet this requirement for the SNF QRP. We also noted at that time our intent to raise the proposed 80 percent threshold in subsequent program years.[247]

We proposed that, beginning with the FY 2026 SNF QRP, SNFs would be required to report 100 percent of the required quality measure data and standardized patient assessment data collected using the MDS on at least 90 percent of the assessments they submit through the CMS-designated submission system.

Complete data are needed to help ensure the validity and reliability of SNF QRP data items, including risk-adjustment models. The proposed threshold of 90 percent is based on the need for substantially complete records, which allows appropriate analysis of SNF QRP measure data for the purposes of updating quality measure specifications as they undergo yearly and triennial measure maintenance reviews with the CBE. Additionally, we want to ensure complete SNF QRP measure data from SNFs, which will ultimately be reported to the public, allowing our beneficiaries to gain a more complete understanding of SNF performance related to these metrics, helping them to make informed healthcare choices. Finally, the proposal would contribute to further alignment of data completion thresholds across the PAC settings.

We believe SNFs should be able to meet the proposed requirement for the SNF QRP. Our data suggest that the majority of SNFs are already in compliance with, or exceeding, the proposed threshold. The complete list of items required under the SNF QRP is updated annually and posted on the SNF QRP Measures and Technical Information page.[248]

We proposed that SNFs would be required to comply with the proposed new data completion threshold beginning with the FY 2026 SNF QRP. Starting in CY 2024, SNFs would be required to report 100 percent of the required quality measures data and standardized patient assessment data collected using the MDS on at least 90 percent of all assessments submitted January 1 through December 31 for that calendar year's payment determination. Any SNF that does not meet the proposed requirement will be subject to a reduction of 2 percentage points to the applicable FY APU beginning with the FY 2026 SNF QRP. We proposed to update § 413.360(f) of our regulations to reflect this new policy, as well as to clarify and make non-substantive edits to improve clarity of the regulation.

We solicited public comment on the proposed schedule for the increase of SNF QRP data completion thresholds for the MDS data items beginning with the FY 2026 program year. The following is a summary of the comments we received and our responses.

Comment: A number of commenters opposed our proposal to increase the SNF QRP data completion thresholds for MDS data items beginning with the FY 2026 SNF QRP because they believe SNFs need more time to adjust to the collection of the new standardized patient assessment data elements that begins October 1, 2023. These commenters do not believe that 3 months is adequate time for SNFs to adjust to the new data elements. One of these commenters noted that the proposed increase in the data completion threshold comes at a time when CMS is significantly expanding

[246] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-483/subpart-B/section-483.20.*

[247] 80 FR 22077; 80 FR 46458.

[248] The SNF QRP Measures and Technical Information page. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

the MDS 3.0, and there is additional health IT programming that will need to be done to accommodate these data as well. One of these commenters suggested that CMS apply the higher 90 percent threshold only to the current required data elements and implement a 75 percent threshold for the new standardized patient assessment data element.

Response: We acknowledge the commenters' concerns, but as we stated in the SNF PPS proposed rule, our data suggest that the majority of SNFs are already in compliance with, or exceeding, this proposed threshold. As the commenters noted, SNFs will begin collecting new standardized patient assessment data elements beginning October 1, 2023.[249] However, many of these items are not ''new'' to SNFs. SNFs have been collecting the Brief Interview for Mental Status (BIMS), Confusion Assessment Method (CAM©), the Patient Health Questionnaire (PHQ), some of the Nutritional Approaches, and even some of the Special Treatments, Procedures, and Programs for several years, but they have not counted toward the SNF's data completion threshold for the SNF QRP. We also want to note that three of the new items have a response option (''None of the above'') that SNFs can select for residents who are not receiving special nutritional approaches, high-risk drug classes, and special treatments, procedures, and programs. When ''None of the above'' is selected, 46 of the items are eliminated and SNFs do not have to complete them. To support SNFs, we have already begun to provide extensive education and training opportunities on the standardized patient assessment data elements for SNFs, and will continue to do so, in addition to answering all questions through our SNF QRP Helpdesk.

We also do not believe it would be appropriate to implement a lower threshold for the new standardized patient assessment data elements. As noted earlier, many of these items are not ''new'' to SNFs, even though they did not count towards the SNF's data completion threshold for the SNF QRP. We must maintain our commitment to the quality of care for all residents, and we continue to believe that the collection of the standardized patient assessment data elements and TOH Information measures will contribute to this effort. We note that in response to the ''Request for Information to Close the Health Equity Gap'' in the FY 2022 SNF PPS proposed rule (86 FR 20000), we heard from interested parties that it is important to gather additional information about race, ethnicity, gender, language, and other SDOH, and some SNFs noted they had already begun to collect some of this information for use in their operations. We believe capturing complete information on these new items is equally important and therefore do not plan to implement a lower threshold for these items.

Comment: One commenter noted it would place additional burden on the important role of the Nurse Assessment Coordinators at a time when they are already in short supply. Another suggested that because SNF residents are often extremely sick, there are often situations outside of the facility's control that may prevent them from being able to complete an MDS in its entirety. Another commenter echoed that point and added that for facilities that serve larger proportions of complex and/or acutely ill residents, these cases are more frequent, and that 20 percent buffer is necessary. This commenter also added that CMS rationale for increasing the data completion threshold—that is, that the majority of SNFs already meet or exceed the 90 percent threshold—is moot since these SNFs clearly do not need the motivation of a higher threshold to report a larger proportion of complete assessments.

Response: While we acknowledge the impacts of the COVID–19 PHE on the healthcare system, including staffing shortages, it also makes it especially important now to monitor quality of care.[250] Still, we are mindful of burden that may occur from the collection and reporting of our measures. We emphasize, however, that several of the standardized patient assessment data elements reflect activities that align with the existing Requirements of Participation for SNFs.[251] As a result, the information gathered will reflect a process that SNFs should already be conducting and will demonstrate the quality of care provided by SNFs. Additionally, for each of the items, the MDS RAI manual provides instructions for how to code the items if the item does not apply to the resident or the resident is unable to respond. Selecting these responses when applicable counts toward the data completion threshold. Additionally, the assessments of the special services, treatments, and interventions with multiple responses are formatted as a ''check all that apply'' format. Therefore, when treatments do not apply, the assessor need only check one row for ''None of the Above,'' and the data completion requirement is met, and when a resident has to leave emergently, the resident interview questions are not required.

Finally, we do not believe that shortages in staffing will affect implementation of the new MDS because many of the data elements adopted as standardized patient assessment data elements in the FY 2020 SNF PPS final rule are already collected on the MDS 1.17.2 using current SNF staffing levels. Therefore, MDS 1.18.11 results in fewer ''new'' standardized patient assessment data elements for SNFs, as compared to other PAC settings.

Comment: One commenter noted that starting with FY 2026, if finalized, SNFs will have additional reporting requirements for weekly submissions to the approved vendor for the CoreQ: SS Discharge measure. This commenter suggested that delaying the threshold increase would allow time to analyze whether the increase in data elements significantly impacts the SNF's ability to maintain compliance with the QRP requirements.

Response: As described in section VII.C.2.a.(5)(b) of this final rule, we have decided at this time, not to finalize the proposal to add the CoreQ: SS DC measure beginning with the FY 2026 SNF QRP.

After consideration of the public comments we received, we are finalizing our proposal to require SNFs to report 100 percent of the required quality measures data and standardized patient assessment data collected using the MDS on at least 90 percent of all assessments submitted beginning with the FY 2026 SNF QRP as proposed.

G. Policies Regarding Public Display of Measure Data for the SNF QRP

1. Background

Section 1899B(g) of the Act requires the Secretary to establish procedures for making the SNF QRP data available to the public, including the performance of individual SNFs, after ensuring that SNFs have the opportunity to review their data prior to public display. For a more detailed discussion about our

[249] A list of the new and revised standardized patient assessment data elements to be collected beginning October 1, 2023 can be found in the FY 2025 SNF QRP APU Table for Reporting Assessment Based Measures and Standardized Patient Assessment Data Elements document available here: *https://www.cms.gov/files/document/fy-2025-snf-qrp-apu-table-reporting-assessment-based-measures-and-standardized-patient-assessment.pdf.*

[250] *https://psnet.ahrq.gov/primer/nursing-and-patient-safety.*

[251] Code of Federal Regulations. Title 42—Public Health. Part 483—Requirements for States and Long Term Care Facilities. *https://www.govinfo.gov/content/pkg/CFR-2018-title42-vol5/xml/CFR-2018-title42-vol5-part483.xml.*

policies regarding public display of SNF QRP measure data and procedures for the SNF's opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

2. Public Reporting of the Transfer of Health Information to the Provider—Post-Acute Care Measure and Transfer of Health Information to the Patient—Post-Acute Care Measure Beginning With the FY 2025 SNF QRP

We proposed to begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider); and (2) TOH Information to the Patient—PAC Measure (TOH-Patient) beginning with the October 2025 Care Compare refresh or as soon as technically feasible.

We adopted these measures in the FY 2020 SNF PPS final rule (84 FR 38761 through 38764). In response to the COVID–19 PHE, we released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for collection and reporting of the TOH-Provider and TOH-Patient measures to October 1 of the year that is at least 2 full fiscal years after the end of the COVID–19 PHE. Subsequently, in the FY 2023 SNF PPS final rule (87 FR 47502), the compliance date for the collection and reporting of the TOH-Provider and TOH-Patient measures was revised to October 1, 2023. Data collection for these two assessment-based measures will begin with residents discharged on or after October 1, 2023.

We proposed to publicly display data for these two assessment-based measures based on four rolling quarters of data, initially using discharges from January 1, 2024, through December 31, 2024 (Quarter 1 2024 through Quarter 4 2024), and to begin publicly reporting these measures with the October 2025 refresh of Care Compare, or as soon as technically feasible. To ensure the statistical reliability of the data, we proposed that we would not publicly report a SNF's performance on a measure if the SNF had fewer than 20 eligible cases in any four consecutive rolling quarters for that measure. SNFs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/resident stays is too small to report.''

We solicited public comment on our proposal for the public display of the (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider), and (2) Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure (TOH-Patient) assessment-based measures. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to publicly report the Transfer of Health Information to the Provider-PAC Measure and the Transfer of Health Information to the Patient-PAC Measure beginning with the October 2024 Care Compare refresh or as soon as possible. One commenter expressed their appreciation at CMS' decision to delay the implementation of these process measures during the COVID–19 PHE and stated their members are in a better position to be successful with these measures with the timelines presented in the proposed rule.

Another commenter supported these two measures as a starting point to reflect that health information is shared with the next applicable setting as well as the resident.

Response: We appreciate these commenters' support for the proposed public reporting of these measures.

Comment: Two commenters were not supportive of the proposal. One of these commenters believed the publication of the information will be confusing for consumers and burdensome to SNFs.

Response: We want to clarify that the proposal would add no additional reporting requirements to the SNF QRP. Additionally, we believe that publicly reporting these measures will provide consumers with meaningful information about a SNF's communication of health information, which is critical to ensuring safe and effective transitions from one healthcare setting to another. We work closely with our Office of Communications and consumer groups when onboarding new measures to the Care Compare websites, and we will do the same with the TOH-Patient and TOH-Provider measures.

Comment: Another commenter stated CMS should reconsider publicly reporting the information, and requested CMS delay public display until 2025, using information based on discharges beginning January 1, 2024. They stated the calculation of the measure is confusing, and instructions provided by CMS and its contractors were not made clear until very recently.

Response: SNFs will begin collecting the TOH Information data elements for all residents discharged beginning October 1, 2023. Consistent with the implementation of these measures in other PAC settings, we began providing provider education earlier this year. Additionally, our helpdesks have been responding to provider questions about these measures since the compliance date for the collection of the TOH Information data elements was finalized in the FY 2023 SNF PPS final rule (87 FR 47544 through 47551). We proposed using data collected from January 1, 2024 through December 31, 2024, and believe this will provide SNFs ample time to adjust to their collection. This schedule is consistent with the inaugural display of other new SNF QRP measures.

Comment: We received several additional comments that were outside the scope of our proposal for public reporting of these measures. One commenter urged CMS to expand the measure to include additional information at the time of transfer to facilitate appropriate infection prevention and control, such as other transmission-based precautions a resident may have, presence of indwelling catheters and a resident's vaccination status. One commenter suggested that CMS should consider that sharing the medication list with the resident may not be enough if the resident is unable to understand or follow that list and that it might be more appropriate to assess whether, in those instances, the list was provided to the resident and the family or caregiver. One commenter noted that providing an electronic list to the next provider can be problematic when the PAC provider and the resident's primary care practitioner utilize different Electronic Medical Record (EMR) systems.

Response: We thank the commenters for bringing these issues to our attention and will take these comments into consideration for potential policy refinements.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider); and (2) TOH Information to the Patient—PAC Measure (TOH-Patient) beginning with the October 2025 Care Compare refresh or as soon as technically feasible.

3. Public Reporting of the Discharge Function Score Measure Beginning With the FY 2025 SNF QRP

We proposed to begin publicly displaying data for the DC Function measure beginning with the October 2024 refresh of Care Compare, or as soon as technically feasible, using data collected from January 1, 2023 through December 31, 2023 (Quarter 1 2023 through Quarter 4 2023). We proposed, that a SNF's DC Function score would be displayed based on four quarters of data. Provider preview reports would be

distributed in July 2024, or as soon as technically feasible. Thereafter, a SNF's DC Function score would be publicly displayed based on four quarters of data and updated quarterly. To ensure the statistical reliability of the data, we proposed that we would not publicly report a SNF's performance on the measure if the SNF had fewer than 20 eligible cases in any quarter. SNFs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/resident stays is too small to report.''

We solicited public comment on the proposal for the public display of the Discharge Function Score assessment-based measure beginning with the October 2024 refresh of Care Compare, or as soon as technically feasible. The following is a summary of the comments we received and our responses.

Comment: Two commenters provided support to publicly report the DC Function measure.

Response: We thank the commenters for their support to publicly report the proposed measure.

Comment: One commenter opposed public reporting for this measure as it may inappropriately skew the decision-making process when residents and facilities are reviewing SNF performance prior to admission to a SNF. Although the commenter does not explicitly state the rationale for how this measure would skew decision-making processes, they urge CMS to wait to adopt this measure until it has undergone CBE endorsement.

Response: We do not believe the publication of this measure inappropriately skews residents' decision-making process, and on the contrary will allow Care Compare users to base healthcare decisions on a measure that, as testing demonstrated, more accurately measures functional ability. We direct readers to section VII.C.1.b.1.b. of this final rule, and the technical report for detailed measures testing results demonstrating that the measure provides meaningful information which can be used to improve quality of care, and to the TEP report summaries [252] [253] which detail TEP support for the proposed measure concept. We also acknowledge the importance of the CBE endorsement process and plan to submit the proposed measure for CBE endorsement in the future.

Comment: One commenter expressed concern about consumer confusion with the public reporting of multiple SNF functional outcome measures, as the DC Function measure correlates highly with the Discharge Self-Care Score and Discharge Mobility Score measures. This commenter asks CMS to consider whether reporting only the DC Function measure is sufficient to help the public make informed care decisions.

Response: We work closely with our Office of Communications and consumer groups when onboarding new measures to the Care Compare websites, and we will do the same with the DC Function measure. We will also provide additional training and outreach materials for SNFs before the measure is publicly reported.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the DC Function measure beginning with the October 2024 Care Compare refresh or as soon as technically feasible.

4. Public Reporting of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2026 SNF QRP

We proposed to begin publicly displaying data for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the October 2025 refresh of Care Compare or as soon as technically feasible using data collected for Q4 2024 (October 1, 2024 through December 31, 2024). We proposed that a SNF's Patient/Resident COVID–19 Vaccine percent of residents who are up to date would be displayed based on one quarter of data. Provider preview reports would be distributed in July 2025 for data collected in Quarter 4 of CY 2024, or as soon as technically feasible. Thereafter, the percent of SNF residents who are up to date with their COVID–19 vaccinations would be publicly displayed based on 1 quarter of data updated quarterly. To ensure the statistical reliability of the data, we proposed that we would not publicly report a SNF's performance on the measure if the SNF had fewer than 20 eligible cases in any quarter. SNFs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/resident stays is too small to report.''

We solicited public comment on the proposal for the public display of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the October 2025 refresh of Care Compare, or as soon as technically feasible. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported public reporting of this measure on Care Compare, to aid beneficiaries and families in selecting a facility, while protecting resident privacy. One commenter suggested that CMS provide contextual guidance that the vaccine is not mandatory and that community vaccine hesitancy factors may influence the vaccination rate in any particular SNF. One commenter suggested that CMS should explicitly detail alongside any public reporting the scoring methodology and exclusions for the measure. Another commenter noted that these data on Care Compare should be coordinated with existing measures of staff and resident COVID–19 vaccination rates to avoid confusion and duplication. They also suggested that reported data on Care Compare include demographic information and be stratified by race, ethnicity and other social risk factors to highlight potential disparities and help address health equity gaps. One commenter noted that if adopted this measure should not be reported through the NHSN.

Response: We thank the commenter for their support and appreciate the additional suggestions provide by other commenters. We work closely with our Office of Communications and consumer groups when onboarding new measures to the Care Compare websites, and we will do the same with the Patient/Resident COVID–19 Vaccine measure. We will also provide additional training and outreach materials for SNFs before the measure is publicly reported. Additionally, we set public reporting thresholds for each measure to ensure we are protecting resident privacy. We also did not propose stratified reporting of these data for this measure; however, we continue to take all concerns, comments, and suggestions into account for future development and expansion of policies to advance health equity across the SNF QRP, including by supporting SNFs in their efforts to ensure equity for all of their residents, and to identify opportunities for improvements in health outcomes. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary. Lastly, this SNF QRP measure will be reported on Care Compare using data collected

[252] Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report (July 2021 TEP).) is available at *https://mms-test.battelle.org/sites/default/files/TEP-Summary-Report-PAC-Function.pdf*.

[253] Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report (January 2022 TEP) is available at *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf*.

through an assessment item on the MDS. This measure was not proposed to be reported through the NHSN.

Comment: One commenter disagrees with CMS's statement that public reporting of the resident/patients who are up to date measure ''would provide residents and caregivers, including those who are at high risk for developing serious complications from COVID–19, with valuable information they can consider when choosing a SNF.'' They believe the measure reflects only short-stay residents who are a small portion of the total resident population that is generally not segregated from the broader population, and no longer resides in the nursing home. They noted that the measure tells nothing about risks to potential residents due to the vaccination status of the individuals with whom they will be living and interacting, and that this information is not beneficial to individuals considering SNF care. Another commenter was concerned that scores from both sets of data would be publicly reported and could lead to confusion when a SNF's scores appearing on Care Compare would display two different data sets for the same measure.

Response: We acknowledge that the proposed measure captures only short-stay residents. As mentioned in section VII.C.2.b.2. of this final rule, residents receiving SNF care under the Medicare fee-for-service program may differ from residents receiving long-term care in nursing homes. We also note that SNFs are not required to report beneficiary-level data to the CDC's NHSN, and data from non-CAH swing bed units are not included in the COVID–19 vaccination data reported to the NHSN by nursing homes. Therefore, reporting of this data through the MDS would capture additional resident characteristics and resident populations that may not be covered under the NHSN reporting. Additionally, we believe that adding this measure to the SNF QRP as an assessment-based measure will give SNFs more visibility into their patient-level vaccination rates in order to identify opportunities to improve COVID–19 vaccination rates.

We also acknowledge the commenter's concern regarding the public display of resident vaccination rates using NHSN and MDS data. We work closely with the Office of Communications and consumer groups when onboarding new measures to the Care Compare websites and will take this concern under consideration.

Comment: One commenter raised concerns regarding the reliability of this data collected due to a moving-target definition in addition to there being a lag time from when the vaccine is administered, the data gathered and submitted, and its eventual display online.

Response: We intend to publicly report one quarter of data, so that each Care Compare refresh would include the most up to date information available. We believe this mitigates concerns that the data would not reflect ''recent'' information to consumers.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the Patient/Resident COVID–19 Vaccine measure beginning with the October 2025 Care Compare refresh or as soon as technically feasible.

VIII. Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program

A. Statutory Background

Through the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program, we award incentive payments to SNFs to encourage improvements in the quality of care provided to Medicare beneficiaries. The SNF VBP Program is authorized by section 1888(h) to the Act, and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing bed rural hospitals. We believe the SNF VBP Program has helped to transform how Medicare payment is made for SNF care, moving increasingly towards rewarding better value and outcomes instead of merely rewarding volume. Our codified policies for the SNF VBP Program can be found in our regulations at 42 CFR 413.337(f) and 413.338.

B. SNF VBP Program Measures

1. Background

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the following prior final rules:

- In the FY 2016 SNF PPS final rule (80 FR 46411 through 46419), we finalized the Skilled Nursing Facility 30 Day All-Cause Readmission Measure (SNFRM) as required under section 1888(g)(1) of the Act.
- In the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission (SNFPPR) Measure as required under section 1888(g)(2) of the Act.
- In the FY 2020 SNF PPS final rule (84 FR 38821 through 38822), we updated the name of the SNFPPR measure to the ''Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure'' (§ 413.338(a)(14)).
- In the FY 2021 SNF PPS final rule (85 FR 47624), we amended the definition of ''SNF Readmission Measure'' in our regulations to reflect the updated name for the SNFPPR measure.
- In the FY 2022 SNF PPS final rule (86 FR 42503 through 42507), we finalized a measure suppression policy for the duration of the PHE for COVID–19, and finalized suppression of the SNFRM for scoring and payment purposes for the FY 2022 SNF VBP Program. We also updated the lookback period for risk-adjustment in the FY 2023 performance period (FY 2021).
- In the FY 2023 SNF PPS final rule (87 FR 47559 through 47580), we finalized suppression of the SNFRM for scoring and payment purposes for the FY 2023 SNF VBP Program. We also modified the SNFRM beginning with the FY 2023 program year by adding a risk-adjustment variable for both patients with COVID–19 during the prior proximal hospitalization (PPH) and patients with a history of COVID–19. We also finalized three new quality measures for the SNF VBP Program as permitted under section 1888(h)(2)(A)(ii) of the Act. We finalized two new measures beginning with the FY 2026 program year: (1) Skilled Nursing Facility Healthcare Associated Infections Requiring Hospitalization (SNF HAI) measure; and (2) Total Nursing Hours per Resident Day Staffing (Total Nurse Staffing) measure. We finalized an additional measure beginning with the FY 2027 program year: Discharge to Community—Post-Acute Care Measure for Skilled Nursing Facilities (DTC PAC SNF) measure.

2. Refinements to the SNFPPR Measure Specifications and Updates to the Measure Name

a. Background

Section 1888(g)(2) of the Act requires the Secretary to specify a resource use measure that reflects an all-condition, risk-adjusted potentially preventable hospital readmission rate for skilled nursing facilities. To meet this statutory requirement, we finalized the Skilled Nursing Facility Potentially Preventable Readmission (SNFPPR) measure in the FY 2017 SNF PPS final rule (81 FR 51987 through 51995). In the FY 2020 SNF PPS final rule (84 FR 38821 through 38822), we updated the SNFPPR measure name to the Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure, while maintaining SNFPPR as the measure short name.

Although our testing results indicated that the SNFPPR measure was sufficiently developed, valid, and reliable for use in the SNF VBP Program at the time we adopted it, we have since engaged in additional measure development work to further align the measure's specifications with the specifications of other potentially preventable readmission (PPR) measures, including the SNF PPR post-discharge (PD) measure specified for the SNF QRP, and the within-stay PPR measure used in the IRF QRP. Based on those efforts, we proposed to refine the SNFPPR measure specifications as follows: (1) changing the outcome observation window from a fixed 30-day window following acute care hospital discharge to within the SNF stay; and (2) changing the length of time allowed between a qualifying prior proximal inpatient discharge (that is, the inpatient discharge that occurs prior to admission to the index SNF stay) and SNF admission from one day to 30 days. To align with those measure refinements, we also proposed to update the measure name to the ''Skilled Nursing Facility Within-Stay Potentially Preventable Readmission (SNF WS PPR) Measure.''

b. Overview of the Updated Measure

The SNF WS PPR measure estimates the risk-standardized rate of unplanned, potentially preventable readmissions (PPR) that occur during SNF stays among Medicare fee-for-service (FFS) beneficiaries. Specifically, this outcome measure reflects readmission rates for SNF residents who are readmitted to a short-stay acute-care hospital or long-term care hospital (LTCH) with a principal diagnosis considered to be unplanned and potentially preventable while within SNF care. The measure is risk-adjusted and calculated using 2 consecutive years of Medicare FFS claims data.

We have tested the updated SNF WS PPR measure for reliability and validity. The random split-half correlation tests indicated good reliability with the intraclass correlation coefficient being notably better than that of the SNFRM. In addition, we tested the validity of the SNF WS PPR measure by comparing SNF WS PPR measure scores with those of nine other measures. The testing results indicated that the SNF WS PPR measure is not duplicative of those nine measures and provides unique information about quality of care not captured by the other nine measures. Validity tests also showed that the measure can accurately predict PPRs while controlling for differences in resident case-mix. We refer readers to the SNF WS PPR measure technical specifications available at *https://www.cms.gov/files/document/snfvbp-snfwsppr-draft-technical-measure-specification.pdf.*

(1) Measure Applications Partnership (MAP) Review

We included the SNF WS PPR measure as a SNF VBP measure under consideration in the publicly available ''2022 Measures Under Consideration List.'' [254] The MAP offered conditional support of the SNF WS PPR measure for rulemaking, contingent upon endorsement by the consensus-based entity, noting that the measure would add value to the Program because PPRs are disruptive and burdensome to patients. We refer readers to the final 2022–2023 MAP recommendations for further details available at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

c. Data Sources

The SNF WS PPR measure is calculated using 2 consecutive years of Medicare FFS claims data to estimate the risk-standardized rate of unplanned PPRs that occur during SNF stays. Specifically, the stay construction, exclusions, and risk-adjustment model utilize data from the Medicare eligibility files and inpatient hospital claims. Calculating the SNF WS PPR measure using 2 years of data improved the measure's statistical reliability relative to 1 year of data, which is used in the current version of the SNFPPR measure. Because the SNF WS PPR measure is calculated entirely using administrative data, we stated that our proposed adoption of the measure would not impose any additional data collection or submission burden for SNFs.

d. Measure Specifications

(1) Denominator

The population included in the measure denominator is Medicare FFS beneficiaries who are admitted to a SNF during a 2-year measurement period who are not then excluded based on the measure exclusion criteria, which we describe in the next section. For SNF residents with multiple SNF stays during the 2-year readmission window, each of those SNF stays is eligible for inclusion in the measure. In addition, the index SNF admission must have occurred within 30 days of discharge from a prior proximal hospital (PPH) stay, which is defined in the measure specifications as an inpatient stay in an IPPS hospital, a CAH, or an inpatient psychiatric facility. Residents who expire during the readmission window are included in the measure.

The measure denominator is the risk-adjusted ''expected'' number of residents with a PPR that occurred during the SNF stay. This estimate includes risk adjustment for certain resident characteristics without the facility effect, which we further discuss in section VIII.B.2.e. of this final rule. The ''expected'' number of residents with a PPR is derived from the predicted number of residents with a PPR if the same residents were treated at the average SNF, which is defined for purposes of this measure as a SNF whose facility effect is zero.

(2) Denominator Exclusions

A SNF stay is excluded from the measure denominator if it meets at least one of the following conditions:

- The SNF resident is less than 18 years old.
- The SNF resident did not have at least 12 months of continuous FFS Medicare enrollment prior to SNF admission, which is defined as the month of SNF admission and the 11 months prior to that admission.
- The SNF resident did not have continuous FFS Medicare enrollment for the entire risk period (defined as enrollment during the month of SNF admission through the month of SNF discharge).
- SNF stays where there was a gap of greater than 30 days between discharge from the PPH and the SNF admission.
- The SNF resident was discharged from the SNF against medical advice.
- SNF stays in which the principal diagnosis for the PPH was for the medical treatment of cancer. Residents with cancer whose principal diagnosis from the PPH was for other medical diagnoses or for surgical treatment of their cancer remain included in the measure.
- SNF stays in which the principle diagnosis for the PPH was for pregnancy (this is an atypical reason for resident to be admitted to SNFs).
- The SNF resident who the SNF subsequently transfers to a Federal hospital. A transfer to a Federal hospital is identified when discharge code 43 is entered for the patient discharge status field on the Medicare claim.
- The SNF resident received care from a provider outside of the United States, Puerto Rico, or a U.S. territory, as identified by the provider's CCN on the Medicare claim.
- SNF stays with data that are problematic (for example, anomalous

[254] 2022 Measures Under Consideration Spreadsheet available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

records for hospital stays that overlap wholly or in part or are otherwise erroneous or contradictory).

- SNF stays that occurred in a CAH swing bed.

For additional details on the denominator exclusions, we refer readers to the SNF WS PPR measure technical specifications available at *https://www.cms.gov/files/document/snfvbp-snfwsppr-draft-technical-measure-specification.pdf.*

(3) Numerator

The numerator is defined as the number of SNF residents included in the measure denominator who also have an unplanned PPR during an index SNF stay. For the purposes of this measure, an unplanned PPR is defined as a readmission from a SNF to an acute care hospital or a long-term care hospital, with a diagnosis considered to be unplanned and potentially preventable. The numerator only includes unplanned PPRs that occur during the within-SNF stay period (that is, from the date of the SNF admission through and including the date of discharge), which can be a hospital readmission that occurs within the SNF stay or a direct transfer to a hospital on the date of the SNF discharge. Because this measure focuses on potentially preventable and *unplanned* readmissions, we do not count planned readmissions in the numerator. Further, because we consider readmissions to inpatient psychiatric facilities to be planned, they are also not counted in the numerator.

The measure numerator is the risk-adjusted ''predicted'' estimate of the number of residents with an unplanned PPR that occurred during a SNF stay. This estimate starts with the unadjusted, observed count of the measure outcome (the number of residents with an unplanned PPR during a SNF stay), which is then risk-adjusted for resident characteristics and a statistical estimate of the SNF's facility effect, to become the risk-adjusted numerator.

e. Risk Adjustment

The SNF WS PPR measure is risk-adjusted to control for risk factor differences across SNF residents and SNF facilities. Specifically, the statistical model utilizes a hierarchical logistic regression to estimate the effect of resident characteristics on the probability of readmission across all SNFs and the effect of each SNF on readmissions that differs from that of the average SNF (''facility effect''). The denominator is risk-adjusted for resident characteristics only, while the numerator is risk-adjusted for both resident characteristics and the facility effect. The specific risk adjustment variables included in the statistical model for this measure are the following:

- Age and sex category.
- Original reason for Medicare entitlement (disability or other).
- Indicator of End-Stage Renal Disease (ESRD).
- Surgery category if present (for example, cardiothoracic, orthopedic), as defined in the Hospital Wide Readmission (HWR) measure model software. The surgical procedures are grouped using the Clinical Classification Software (CCS) classes for ICD–10 procedures developed by the Agency for Healthcare Research and Quality (AHRQ).
- Principal diagnosis on PPH inpatient claim. The ICD–10 codes are grouped clinically using the CCS mappings developed by AHRQ.
- Comorbidities from secondary diagnoses on the PPH inpatient claim and diagnoses from earlier hospital inpatient claims up to 1 year before the date of the index SNF admission (these are clustered using the Hierarchical Condition Categories (HCC) groups used by CMS).
- Length of stay in the PPH (categorical to account for nonlinearity).
- Prior acute intensive care unit (ICU) or critical care unit (CCU) utilization.
- Number of prior acute care hospital discharges in the prior year.

For additional details on the risk adjustment model, we refer readers to the SNF WS PPR measure technical specifications available at *https://www.cms.gov/files/document/snfvbp-snfwsppr-draft-technical-measure-specification.pdf.*

f. Measure Calculation

The SNF WS PPR measure estimates the risk-standardized rate of unplanned PPRs that occur during SNF stays among Medicare FFS beneficiaries. A lower score on this measure indicates better performance. The provider-level risk-standardized readmission rate (RSRR) of unplanned PPRs is calculated by multiplying the standardized risk ratio (SRR) by the mean readmission rate in the population (that is, all Medicare FFS residents included in the measure). The SRR is calculated as the predicted number of readmissions at the SNF divided by the expected number of readmissions for the same residents if treated at the average SNF. For additional details on the calculation method, we refer readers to the SNF WS PPR measure technical specifications available at *https://www.cms.gov/files/document/snfvbp-snfwsppr-draft-technical-measure-specification.pdf.*

g. Scoring of SNF Performance on the SNF WS PPR Measure

(1) Background

In the FY 2017 SNF PPS final rule (81 FR 52000 through 52001), we finalized a policy to invert SNFRM measure rates such that a higher measure rate reflects better performance on the SNFRM. In that final rule, we also stated our belief that this inversion is important for incentivizing improvement in a clear and understandable manner, and because a ''lower is better'' rate could cause confusion among SNFs and the public. In the FY 2023 SNF PPS final rule (87 FR 47568), we applied this policy to the SNF HAI measure such that a higher measure rate reflects better performance on the SNF HAI measure. We also stated our intent to apply this inversion scoring policy to all measures in the Program for which the calculation produces a ''lower is better'' measure rate. We continue to believe that inverting measure rates such that a higher measure rate reflects better performance on a measure is important for incentivizing improvement in a clear and understandable manner.

The measure rate inversion scoring policy does not change the measure specifications or the calculation method. We use this measure rate inversion only as part of the scoring methodology under the SNF VBP Program. The measure rate inversion is part of the methodology we use to generate measure scores, and resulting SNF Performance Scores, that are clear and understandable for SNFs and the public.

(2) Inversion of the SNF WS PPR Measure Rate for SNF VBP Scoring Purposes

In the previous section, we stated that a lower risk-standardized rate for the SNF WS PPR measure indicates better performance. Therefore, we proposed to apply our measure rate inversion scoring policy to the SNF WS PPR measure because a ''lower is better'' rate could cause confusion among SNFs and the public. Specifically, we proposed to calculate the scores for this measure for the SNF VBP Program by inverting the SNF WS PPR measure rates using the following calculation:

SNF WS PPR Inverted Rate = 1– Facility's SNF WS PPR Risk Standardized Rate

This calculation will invert SNF WS PPR measure rates such that a higher measure rate would reflect better performance.

h. Confidential Feedback Reports and Public Reporting for the SNF WS PPR Measure

Our confidential feedback reports and public reporting policies are codified at § 413.338(f) of our regulations. In the FY 2023 SNF PPS final rule (87 FR 47591 through 47592), we revised our regulations such that the confidential feedback reports and public reporting policies apply to each measure specified for a fiscal year, which includes the SNF WS PPR measure beginning with the FY 2028 program year.

We solicited public comment on our proposal to refine the measure specifications for the SNFPPR measure, and our proposal to update the measure's name to the ''Skilled Nursing Facility Within-Stay Potentially Preventable Readmissions (SNF WS PPR) measure.'' We also solicited public comment on our proposal to invert the SNF WS PPR measure rate for SNF VBP Program scoring purposes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to refine the SNFPPR measure specifications and update the measure name to the SNF WS PPR measure because those proposals more appropriately align the measure with changes and improvements within the SNF's control. Specifically, commenters supported the change to a within-SNF stay readmission specification because it allows for a fairer comparison of SNF performance given the socioeconomic and other community factors outside a SNF's control that may impact hospital readmissions during the periods before SNF admission and after SNF discharge.

Response: We thank the commenters for their support. We agree that this measure refinement allows us to accurately measure the rates of PPRs across SNFs and to assess performance based on factors within a SNF's control.

Comment: One commenter, while supporting the proposal to refine the SNFPPR measure specifications and update the measure name generally, recommended that CMS delay adoption of the SNF WS PPR measures until it has been endorsed by the consensus-based entity (CBE).

Response: SNF VBP measures are not required to be endorsed by the CBE to be included in the Program. We will consider submitting this measure for endorsement by the CBE in the future.

Comment: One commenter expressed concern about the proposal to implement the SNF WS PPR measure because we would score it using predicted and expected outcomes for residents, which may not be accurate.

Response: We do not agree with commenter's concern regarding the accuracy and use of predicted and expected outcomes for residents as part of the calculation for the SNF WS PPR measure. The ''expected'' and ''predicted'' values are estimates of the measure outcome (denominator and numerator, respectively) and are calculated by risk adjusting the data obtained from the Medicare FFS claims. As we discuss in section VIII.G. of this final rule, claims data are validated for accuracy by Medicare Administrative Contractors (MACs) and therefore, we believe these data are sufficiently validated and accurate for use in calculating SNF VBP claims-based measures. Further, the risk adjustment model helps ensure we are assessing SNF performance based on the quality of care delivered by SNFs. We also note that the current measure (SNFRM) is calculated in a similar manner.

Comment: A few commenters expressed concern about the proposal to implement the SNF WS PPR measure, due to the potential to attribute preventable hospital readmissions to the SNF when the hospital readmission is due to other factors, such as being prematurely discharged from a hospital or if a patient's condition worsened before admission to a SNF. Specifically, one commenter expressed concern that refining the SNFPPR measure specifications to increase the number of days between the hospital inpatient discharge and SNF admission could increase the potential for factors outside the hospital or SNF's control to influence a resident's condition prior to the SNF admission. A few commenters recommended that CMS consider expanding the exclusion criteria to exclude residents with more complex care and applying appropriate risk adjustment. One commenter expressed concern that the SNF WS PPR measure could produce counterproductive SNF behavior, such as incentivizing SNFs to not admit patients discharged from the hospital who have multiple co-morbidities and are at higher risk of being readmitted to the hospital, and to only admit those perceived to have a lower risk of hospital readmission. One commenter recommended that CMS continue to measure how transitioning to the SNF WS PPR measure impacts the conditions residents present with at admission.

Response: We recognize that the measure cannot completely eliminate the potential risk of attributing a PPR to a SNF when that readmission occurred due to factors outside the SNFs control. However, we believe that the SNF WS PPR measure specifications minimize that risk to the extent feasible. For example, the SNF WS PPR measure has a robust risk-adjustment model that controls for numerous variables including comorbidities, principal diagnoses for the prior proximal hospital inpatient claim, and measures of prior acute care utilization. We also note that the WS PPR definition was developed based on findings from an environmental scan, empirical analyses, and clinical team evaluations to ensure that hospital readmissions included in this measure are potentially preventable and unplanned, and that readmissions include only PPR conditions associated with post-acute care. For additional details on the PPR definition used for the measure, we refer commenters to the SNF WS PPR measure technical specifications available at *https://www.cms.gov/files/document/snfvbp-snfwsppr-draft-technical-measure-specification.pdf.* In addition, we note that section 1888(g)(2) of the Act requires that the SNF WS PPR measure be ''all-condition,'' which we believe necessitates attributing readmissions to SNFs even in the cases the commenter specified.

The original SNFPPR measure excluded SNF stays with a gap of greater than one day between discharge from the prior proximal hospitalization and SNF admission in order to harmonize with the SNFRM measure specifications. We received public comments and feedback from a Technical Expert Panel (TEP) expressing concern with the 1-day prior proximal hospitalization lookback window noting that this 1-day lookback window does not consider medically complex patients and that this criterion did not align with the measure specifications for other PPR measures. In response to that feedback, we refined the SNF WS PPR measure specifications such that the SNF admission must occur within 30 days of discharge from the prior proximal hospitalization. This refinement aligns the SNF WS PPR measure specifications with those of PPR measures used in other CMS Programs, including the SNF PPR post-discharge measure specified for the SNF QRP. We note that the SNF WS PPR measure refinements are associated with improved measure reliability and validity. We intend to monitor performance on this measure as part of ongoing evaluation efforts.

We believe the exclusion criteria for the SNF WS PPR measure, as detailed in section VIII.B.2.d.(2) of this final rule, in addition to the variables included in

the risk-adjustment model, are sufficient for controlling for medically complex residents. For example, the risk-adjustment model includes variables relating to comorbidities, principal diagnoses for the prior proximal hospital inpatient claim, and measures of prior acute care utilization. Therefore, we do not believe it is necessary to expand the exclusion criteria to include medically complex residents at this time. However, we will take this into consideration as we monitor performance on this measure.

After consideration of public comments, we are finalizing the updates to the SNFPPR measure specifications and finalizing our proposal to update the measure's name to the ''Skilled Nursing Facility Within-Stay Potentially Preventable Readmissions (SNF WS PPR) measure.''

3. Replacement of the SNFRM With the SNF WS PPR Measure Beginning With the FY 2028 SNF VBP Program Year

Section 1888(h)(2)(B) of the Act requires the Secretary to apply the measure specified under section 1888(g)(2) of the Act, instead of the measure specified under section 1888(g)(1) of the Act as soon as practicable. To meet that statutory requirement, we proposed to replace the SNFRM with the SNF WS PPR measure beginning with the FY 2028 program year. This is the first program year that we can feasibly implement the SNF WS PPR measure after taking into consideration its proposed performance period and a number of other statutory requirements.

We proposed a 2-year performance period for the proposed SNF WS PPR measure, and we believe the earliest the first performance period can occur is FY 2025 and FY 2026 (October 1, 2024 through September 30, 2026). This will provide us with sufficient time to calculate and announce the performance standards for the SNF WS PPR measure at least 60 days before the beginning of that performance period, as required under section 1888(h)(3)(C) of the Act. Additionally, we are required under section 1888(h)(7) of the Act to announce the net payment adjustments for SNFs no later than 60 days prior to the start of the applicable fiscal year. We calculate these payment adjustments using performance period data. To provide us with sufficient time to calculate and announce the net payment adjustments after the end of the performance period (FY 2025 and FY 2026), we believe the earliest program year in which we can feasibly adopt the proposed SNF WS PPR measure is FY 2028.

We solicited public comment on our proposal to replace the SNFRM with the SNF WS PPR measure beginning with the FY 2028 SNF VBP program year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to replace the SNFRM with the SNF WS PPR measure beginning with the FY 2028 program year because they agreed that this is the earliest CMS can implement this change and that the SNF WS PPR measure is more reflective of actions SNF's can take to reduce hospital readmissions.

Response: We thank the commenters for their support. We agree that replacing the SNFRM with the SNF WS PPR measure more appropriately assesses the quality of care within the SNF's control.

Comment: One commenter opposed the proposal to replace the SNFRM with the SNF WS PPR measure because the SNFRM is already publicly reported and available to consumers.

Response: The commenter is correct in that we do publicly report information on the performance of SNFs with respect to the SNFRM. However, we are required at section 1888(h)(2)(B) of the Act to replace the measure specified under section 1888(g)(1) of the Act, currently the SNFRM, with the measure specified under section 1888(g)(2) of the Act, which we proposed as the SNF WS PPR measure. We will also begin publicly reporting information on the performance of SNFs with respect to the SNF WS PPR measure when the measure is implemented beginning with the FY 2028 SNF VBP program year.

After consideration of public comments, we are finalizing our proposal to replace the SNFRM with the SNF WS PPR measure beginning with the FY 2028 SNF VBP program year.

4. Adoption of Quality Measures for the SNF VBP Expansion Beginning With the FY 2026 Program Year

a. Background

Section 1888(h)(2)(A)(ii) of the Act (as amended by section 111(a)(2)(C) of the CAA 2021) allows the Secretary to expand the SNF VBP Program to include up to 10 quality measures with respect to payments for services furnished on or after October 1, 2023. These measures may include measures of functional status, patient safety, care coordination, or patient experience. Section 1888(h)(2)(A)(ii) of the Act also requires that the Secretary consider and apply, as appropriate, quality measures specified under section 1899B(c)(1) of the Act.

In the FY 2023 SNF PPS final rule (87 FR 47564 through 47580), we adopted the first three measures for the Program expansion: (1) SNF HAI measure; (2) Total Nurse Staffing measure; and (3) DTC PAC SNF measure. We adopted the SNF HAI and Total Nurse Staffing measures beginning with the FY 2026 program year (FY 2024 is the first performance period). We also adopted the DTC PAC SNF measure beginning with the FY 2027 program year (FY 2024 and FY 2025 is the first performance period).

In the proposed rule, we proposed to adopt four additional measures for the Program. We proposed one new measure beginning with the FY 2026 program year (FY 2024 would be the first performance period): Total Nursing Staff Turnover (''Nursing Staff Turnover'') measure. We also proposed to adopt three new measures beginning with the FY 2027 program year (FY 2025 would be the first performance period): (1) Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (''Falls with Major Injury (Long-Stay)'') measure; (2) Discharge Function Score for SNFs (''DC Function measure''); and (3) Number of Hospitalizations per 1,000 Long Stay Resident Days (''Long Stay Hospitalization'') measure.

Therefore, for the FY 2024 performance period, we proposed that SNF data would be collected for five measures: SNFRM, SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, and DTC PAC SNF measures. Performance on the first four measures would affect SNF payment in the FY 2026 program year. Since the DTC PAC SNF measure is a 2-year measure, performance on that measure would affect SNF payment in the FY 2027 program year.

Beginning with the FY 2025 performance period, SNF data would be collected for nine measures: SNFRM, SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, DC Function, Falls with Major Injury (Long-Stay), Long Stay Hospitalization, DTC PAC SNF, and SNF WS PPR measures. Performance on the first eight measures will affect SNF payment in the FY 2027 program year. Since the SNF WS PPR measure is a 2-year measure, performance on this measure will affect SNF payment in the FY 2028 program year. Further, we refer readers to section VIII.B.3. of this final rule for additional details on our replacement of the SNFRM with the SNF WS PPR measure beginning with the FY 2028 program year, which will mean that the FY 2027 and FY 2028

program years will each only have eight measures that affect SNF payment for those program years. Finally, there is no additional burden on SNFs to submit data on these previously adopted and proposed measures for the SNF VBP Program.

Table 15 provides the list of the currently adopted measures and proposed measures for the SNF VBP Program.

TABLE 15—CURRENTLY ADOPTED AND NEWLY PROPOSED SNF VBP MEASURES

Measure name	Measure short name	Measure status	First program year	First performance period *
SNF 30-Day All-Cause Readmission Measure.	SNFRM	Adopted, implemented	** FY 2017	FY 2015.
SNF Healthcare-Associated Infections Requiring Hospitalization Measure.	SNF HAI Measure	Adopted, not implemented.	FY 2026	FY 2024.
Total Nurse Staffing Hours per Resident Day Measure.	Total Nurse Staffing Measure	Adopted, not implemented.	FY 2026	FY 2024.
Total Nursing Staff Turnover Measure	Nursing Staff Turnover Measure	Proposed	+ FY 2026	FY 2024.
Discharge to Community—Post-Acute Care Measure for SNFs.	DTC PAC SNF Measure	Adopted, not implemented.	FY 2027	FY 2024 and FY 2025.
Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) Measure.	Falls with Major Injury (Long-Stay) Measure.	Proposed	+ FY 2027	FY 2025.
Discharge Function Score for SNFs Measure.	DC Function Measure	Proposed	+ FY 2027	FY 2025.
Number of Hospitalizations per 1,000 Long Stay Resident Days Measure.	Long Stay Hospitalization Measure	Proposed	+ FY 2027	FY 2025.
SNF Within-Stay Potentially Preventable Readmissions Measure.	SNF WS PPR Measure	Proposed	+ FY 2028	FY 2025 and FY 2026.

* For each measure, we have adopted a policy to automatically advance the beginning of the performance period by 1-year from the previous program year. We refer readers to section VIII.C.3 of this final rule for additional information.
** Will be replaced with the SNF WS PPR measure beginning with the FY 2028 program year.
+ First program year in which the measure would be included in the Program.

b. Adoption of the Total Nursing Staff Turnover Measure Beginning With the FY 2026 SNF VBP Program Year

(1) Background

Nursing home staffing, including nursing staff turnover, has long been considered an important indicator of nursing home quality.[255] [256] [257] Longer-tenured nursing staff are more familiar with the residents and are better able to detect changes in a resident's condition. They are also more acclimated to their facility's procedures and thus, operate more efficiently. In contrast, higher nursing staff turnover can mean that nursing staff are less familiar with resident needs and facility procedures, which can contribute to lower quality of care.

There is considerable evidence demonstrating the impact of nursing staff turnover on resident outcomes, with higher turnover associated with poorer quality of care.[258] [259] [260] [261] [262] [263] [264] A recent 2019 study comparing nursing home's annualized turnover rates with the overall five-star ratings for the facilities found that the average total nursing staff annual turnover rates were 53.4 percent among one-star nursing homes and 40.7 percent for five-star facilities.[265] The same study found a statistically significant relationship between higher turnover rates and lower performance on clinical quality measures, including hospitalization rates, readmission rates, and emergency department visits.[266] Studies have also shown that nursing staff turnover is a meaningful factor in nursing home quality of care and that staff turnover influences quality outcomes.[267] [268] For example, higher staff turnover is associated with an increased likelihood of receiving an infection control citation.[269]

Recently, the National Academies of Sciences, Engineering, and Medicine formed the Committee on the Quality of Care in Nursing Homes to examine the delivery of care and the complex array of factors that influence the quality of

[255] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[256] Institute of Medicine. Nursing Staff in Hospitals and Nursing Homes: Is It Adequate? Washington, DC: National Academy Press; 1996.

[257] ''To Advance Information on Quality of Care, CMS Makes Nursing Home Staffing Data Available | CMS.'' Accessed December 22, 2022. *https://www.cms.gov/newsroom/press-releases/advance-information-quality-care-cms-makes-nursing-home-staffing-data-available.*

[258] Zheng Q, Williams CS, Shulman ET, White AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. Journal of the American Geriatrics Society. May 2022. doi:10.1111/jgs.17843.

[259] Bostick JE, Rantz MJ, Flesner MK, Riggs CJ. Systematic review of studies of staffing and quality in nursing homes. J Am Med Dir Assoc. 2006;7:366–376. *https://pubmed.ncbi.nlm.nih.gov/16843237/.*

[260] Backhaus R, Verbeek H, van Rossum E, Capezuti E, Hamer JPH. Nursing staffing impact on quality of care in nursing homes: a systemic review of longitudinal studies. J Am Med Dir Assoc. 2014;15(6):383–393. *https://pubmed.ncbi.nlm.nih.gov/24529872/.*

[261] Spilsbury K, Hewitt C, Stirk L, Bowman C. The relationship between nurse staffing and quality of care in nursing homes: a systematic review. Int J Nurs Stud. 2011; 48(6):732–750. *https://pubmed.ncbi.nlm.nih.gov/21397229/.*

[262] Castle N. Nursing home caregiver staffing levels and quality of care: a literature review. J Appl Gerontol. 2008;27:375–405. *https://doi.org/10.1177%2F0733464808321596.*

[263] Spilsbury et al.

[264] Castle NG, Engberg J. Staff turnover and quality of care in nursing homes. Med Care. 2005 Jun;43(6):616–26. doi: 10.1097/01.mlr.0000163661.67170.b9. PMID: 15908857.

[265] Zheng, Q, Williams, CS, Shulman, ET, White, AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. J Am Geriatr Soc. 2022; 70(9): 2508–2516. doi:10.1111/jgs.17843.

[266] Ibid.

[267] Centers for Medicare & Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[268] Loomer, L., Grabowski, DC, Yu, H., & Gandhi, A. (2021). Association between nursing home staff turnover and infection control citations. *Health Services Research. https://doi.org/10.1111/1475-6773.13877.*

[269] Loomer, L., Grabowski, DC, Yu, H., & Gandhi, A. (2021). Association between nursing home staff turnover and infection control citations. *Health Services Research. https://doi.org/10.1111/1475-6773.13877.*

care in nursing homes. The committee published a report in 2022 titled ''The National Imperative to Improve Nursing Home Quality.'' The report details the complex array of factors that influence care quality in nursing homes, including staffing variables such as staffing levels and turnover, and identifies several broad goals and recommendations to improve the quality of care in nursing homes.[270] In the 2022 report, the National Academies of Sciences, Engineering, and Medicine highlighted the association between the high turnover of many nursing home staff, including RNs, and lower quality of care delivery in nursing homes.[271] The report also recognized the need for quality measures that report on turnover rates, citing that increased transparency will improve patient care. Because of its central role in the quality of care for Medicare beneficiaries, HHS and the Biden-Harris Administration are also committed to improving the quality of care in nursing homes with respect to staffing, as stated in the fact sheets entitled ''Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes'' and ''Biden-Harris Administration Announces New Steps to Improve Quality of Nursing Homes.'' [272] [273] While much of this research has been conducted in long-term care facilities or nursing homes, we believe this research is relevant to the SNF setting, because approximately 94 percent of long-term care facilities are dually certified as both SNFs and nursing facilities (86 FR 42508).

In light of the strong association between high nursing staff turnover rates and negative resident outcomes, including the nursing staff turnover measure in the SNF VBP Program will provide a comprehensive assessment of the quality of care provided to residents. This measure may also drive improvements in nursing staff turnover that are likely to translate into positive resident outcomes.

Although the Nursing Staff Turnover measure is not specified under section 1899B(c)(1) of the Act, we believe this measure supports the Program's goals to improve the quality of care provided to Medicare beneficiaries throughout their entire SNF stay. We have long identified staffing as one of the vital components of a SNF's ability to provide quality care and use staffing data to gauge a facility's impact on quality of care in SNFs with more accuracy and efficacy. The proposed measure aligns with the topics listed under section 1888(h)(2)(A)(ii) of the Act and with HHS and Biden-Harris Administration priorities. We also believe that the Nursing Staff Turnover measure would complement the Total Nursing Hours per Resident Day (Total Nurse Staffing) measure, adopted in the FY 2023 SNF PPS final rule (87 FR 47570 through 47576). Together, these measures emphasize and align with our current priorities and focus areas for the Program.

(2) Overview of Measure

The Nursing Staff Turnover measure is a structural measure that uses auditable electronic data reported to CMS' Payroll-Based Journal (PBJ) system to calculate annual turnover rates for nursing staff, including registered nurses (RNs), licensed practical nurses (LPNs), and nurse aides. Given the well-documented impact of nurse staffing on resident outcomes and quality of care, this measure will align the Program with the Care Coordination domain of CMS' Meaningful Measures 2.0 Framework. The Nursing Staff Turnover measure is currently being measured and publicly reported for nursing facilities on the *Care Compare* website *https://www.medicare.gov/care-compare/* and is used in the Five-Star Quality Rating System. For more information on measure specifications and how this measure is used in the Five-Star Quality Rating System, we referred readers to the January 2023 Technical Users' Guide available at *https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/usersguide.pdf.*

This measure is constructed using daily staffing information submitted through the PBJ system by nursing facilities. Specifically, turnover is identified based on gaps in days worked, which helps ensure that Nursing Staff Turnover is defined the same way across all nursing facilities with SNF beds and that it does not depend on termination dates that may be reported inconsistently by these facilities. Individuals are identified based on the employee system ID and SNF identifiers in the PBJ data. We refer readers to the Nursing Staff Turnover measure specifications available at *https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/usersguide.pdf.*

Payroll data are considered the gold standard for nurse staffing measures and are a significant improvement over the manual data previously used, wherein staffing information was calculated based on a form (CMS–671) filled out manually by the facility.[274] The PBJ staffing data are electronically submitted and auditable back to payroll and other verifiable sources. Analyses of PBJ-based staffing measures show a relationship between higher nurse staffing levels and higher ratings for other dimensions of quality such as health inspection survey results and quality measures.[275]

(a) Interested Parties and TEP Input

In 2019 through 2022, CMS tested this measure based on input from the CMS Five-Star Quality Rating Systems' TEP, as well as input from interested parties. We began publicly reporting this measure on the Care Compare website via the Nursing Home Five-Star Rating System in January 2022.

We solicited public feedback on this measure in a ''Request for Comment on Additional SNF VBP Program Measure Considerations for Future Years'' in the FY 2023 SNF PPS proposed rule (87 FR 22786 through 22787). We considered the input we received as we developed our proposal for this measure. We refer readers to the FY 2023 SNF PPS final rule (87 FR 47592 through 475963) for a detailed summary of the feedback we received on this measure.

(b) Measure Applications Partnership (MAP) Review

We included the Nursing Staff Turnover measure as a SNF VBP measure under consideration in the publicly available ''2022 Measures Under Consideration List.'' [276] The MAP offered conditional support of the Nursing Staff Turnover measure for rulemaking, contingent upon endorsement by the consensus-based

[270] National Academies of Sciences, Engineering, and Medicine. 2022. The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff. Washington, DC: The National Academies Press. *https://doi.org/10.17226/26526.*

[271] National Academies of Sciences, Engineering, and Medicine, 2022.

[272] The White House. (2022, February 28). FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes. *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.*

[273] The White House. (2021, October 21). FACT SHEET: Biden-Harris Administration Announces New Steps to Improve Quality of Nursing Homes. *https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/21/fact-sheet-biden-harris-administration-announces-new-steps-to-improve-quality-of-nursing-homes/.*

[274] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-17-NH.pdf.*

[275] Zheng, Q, Williams, CS, Shulman, ET, White, AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. J Am Geriatr Soc. 2022; 70(9): 2508–2516.

[276] 2022 Measures Under Consideration Spreadsheet available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

entity, noting that the measure would add value to the Program because staffing turnover is a longstanding indicator of nursing home quality, and it addresses the Care Coordination domain of the Meaningful Measures 2.0 Framework. We refer readers to the final 2022–2023 MAP recommendations available at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

(3) Data Sources

The Nursing Staff Turnover measure is calculated using auditable, electronic staffing data submitted by each SNF for each quarter through the PBJ system. Specifically, this measure utilizes five data elements from the PBJ data, including employee ID, facility ID, hours worked, work date, and job title code.

(4) Inclusion and Exclusion Criteria

We proposed that SNFs will be excluded from the measure under the following conditions:

- Any SNF with 100 percent total nursing staff turnover for any day in the six-quarter period during which there were at least five eligible nurse staff. A 100 percent daily turnover is typically the result of changes in the employee IDs used by SNFs and does not reflect actual staff turnover.
- SNFs that do not submit staffing data or submit data that are considered invalid (using the current exclusion rules for the staffing domain) for one or more of the quarters used to calculate the Nursing Staff turnover measure.
- SNFs that do not have resident census information (derived from MDS assessments).
- SNFs with fewer than five eligible nurses (RNs, LPNs and nurse aides) in the denominator.

(a) Denominator

The denominator for the Nursing Staff Turnover measure includes all eligible employees, defined as RNs, LPNs, and nurse aides, who are regular employees and agency staff who work at a Medicare certified SNF and use the same job category codes as other nurse staffing measures that are reported on the Care Compare website. For the purposes of this measure, the RN category is defined as RNs (job code 7), RN director of nursing (job code 5), and RNs with administrative duties (job code 6). The LPN category is defined as LPNs (job code 9) and LPNs with administrative duties (job code 8). The nurse aide category is defined as certified nurse aides (job code 10), aides in training (job code 11), and medication aides/technicians (job code 12). This measure only includes eligible employees who work at least 120 hours in a 90-day period. The timeframe for the 90-day period begins on the first workday observed during the quarter prior to the start of the performance period (termed the baseline quarter) and ends on the last workday, of the last month, of the second quarter of the performance period. Eligible employees who work infrequently (that is, those who work fewer than 120 hours during a 90-day period, including those who only occasionally cover shifts at a nursing home) would be excluded from the denominator calculation.

(b) Numerator

The numerator includes eligible employees who were included in the denominator and who are not identified in the PBJ data as having worked at the SNF for at least 60 consecutive days during the performance period. The 60-day gap must start during the period covered by the turnover measure. The turnover date is defined as the last workday prior to the start of the 60-day gap.

(5) Measure Calculation

The Nursing Staff Turnover measure is calculated using six consecutive quarters of PBJ data. Data from a baseline quarter,[277] Q0, along with the first two quarters of the performance period, are used for identifying employees who are eligible to be included in the measure (denominator). The four quarters of data (Q1 through Q4) of the performance period are used for identifying the number of employment spells, defined as a continuous period of work, that ended in turnover (numerator). Data from the sixth quarter (Q5), which occurs after the four-quarter numerator (performance) period, are used to identify gaps in days worked that started in the last 60 days of the fifth quarter (Q4) used for the measure. To calculate the measure score, we first determine the measure denominator by identifying the total number of employment spells, defined as a continuous period of work. For example, for the FY 2026 program year, the denominator will be calculated as the number of eligible employees who worked 120 or more hours in a 90-day period with the first workday of the 90-day period occurring in FY 2023 Q4, the quarter prior to the start of the performance period (Q0), through FY 2024 Q2, the first 2 quarters of the performance period (July 1, 2023 through March 31, 2024). The numerator is calculated as the total number of eligible employees who had a 60-day gap from October 1, 2023 through September 30, 2024 during which they did not work. Data from FY 2025 Q1, defined as Q5 above, is also used to identify gaps that start within 60 days of the end of the performance period (August 2, 2024 through September 30, 2024).

We proposed to calculate the Nursing Staff Turnover measure rate for the SNF VBP Program using the following formula:

$$\textit{Total Nursing Staff Turnover Rate} = \frac{\textit{Total number of employment spells that ended in turnover}}{\textit{Total number of eligible employment spells}}$$

We also note that based on analysis and previous research on turnover measures, and a review by a technical expert panel, the Nursing Staff Turnover measure is not risk-adjusted.

We solicited public comment on our proposal to adopt the Total Nursing Staff Turnover measure beginning with the FY 2026 SNF VBP program year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS's proposal to adopt the Total Nursing Staff Turnover Measure because it provides a meaningful assessment of the quality of care provided to SNF residents.

Response: We thank the commenters for their support. We agree that this measure will provide valuable insight

[277] The baseline quarter is specific to this measure calculation and not related to the SNF VBP Program's measure baseline period, which is part of the performance standards used to score the measure. The baseline quarter is the quarter prior to the first quarter of either the baseline period or the performance period for a program year.

into the quality of care that SNF residents are receiving.

Comment: A few commenters that supported the proposed measure also recommended that a retention measure either be added or used in place of the turnover measure to help incentivize positive behavior by SNFs. One commenter recommended that CMS develop a resident ''dumping'' measure as a metric to reduce facility-initiated transfers and discharges which negatively impact residents and their quality of care.

Response: We thank the commenters for their recommendations and will take this feedback into consideration as we develop additional measures for future rulemaking.

Comment: A few commenters supported the measure generally but recommended that CMS consider a number of factors with respect to both the proposed measure and potential future measures. One commenter suggested that CMS revise the proposed measure to exclude team members that move, or float, within a health system. A few commenters recommended that CMS consider the impact of staffing changes when employees do not work for a period of time that exceeds 60 days (for example, because of family or medical leave) but indicate their intention to return. Several commenters did not support the proposed measure because it does not exclude staff that have taken parental leave or are students or seasonal workers. A few commenters recommended expanding the length of the gap beyond 60 days or providing an adjustment for workers returning from an approved leave. One commenter stated that the proposed measure should take into consideration a differential impact of staff turnover on residents depending on the role of the exiting nursing staff member within the SNF. One commenter suggested that the measure be revised to include all direct care workers and rehabilitation professionals in SNFs because they all impact performance and quality of care. One commenter recommended that CMS monitor the impact of the measure by assessing the relationship between resident outcomes and staff turnover to see if SNFs change their behavior in ways that may lower quality of care.

Response: We carefully considered different turnover specifications, including the 60-day gap threshold for turnover, the inclusion of agency and other types of nursing staff, and the minimum number of hours required to be included in the measure. The final measure specifications were developed based on extensive data analyses, as well as recommendations to us from the project's Technical Expert Panel (TEP) convened by a CMS contractor. We believe this measure, as proposed, is both a reliable and valid measure of nursing staff turnover. We tested the validity of the measure by examining the association between the Nursing Staff Turnover measure and a comprehensive set of measures that capture nursing home quality, including nursing home ratings from Care Compare's Five-Star Quality Rating System and claims-based measures of hospitalizations and outpatient Emergency Department visits for both short- and long-stay residents. We found a consistent and statistically significant relationship between the Nursing Staff Turnover measure and this comprehensive set of measures that capture nursing home quality.[278] For reliability testing, we used split-sample reliability testing. We calculated the Shrout-Fleiss intraclass correlation coefficient (ICC) between the split-half scores to measure reliability. The split-sample ICC was 0.834. The results of this extensive testing indicate the strong relationship between nursing staff turnover, as proposed, and quality of care. It shows that the quality of care is impacted when a caregiver does not report any hours worked for 60 days or more whether they are still officially employed by the SNF or not. Additionally, we conducted analyses that showed a very high correlation in nursing home turnover rates for a measure based on different gaps in days worked (for example, 30, 60, 90 days) suggesting extending the number of days in the gap would have little impact on the measure rate. Lastly, the PBJ data that we use to calculate the turnover measures do not allow us to identify individuals who have taken a period of leave but intend to return to work.

Although we recognize that all staff may have an impact on resident quality, there is substantial literature documenting the relationship between nursing staff turnover and quality.[279] [280] [281] [282] Additional research supports that all nursing staff, including certified nursing assistants and LPNs, play a critical role in providing care to Medicare beneficiaries in SNFs.[283] Because of this extensive evidence, we chose to focus on nursing staff turnover at this time.

Comment: A few commenters supported the proposed measure in concept but expressed concern that the measure may not accurately reflect true nursing staff turnover. A few commenters stated that the measure should distinguish between voluntary and involuntary turnover because they believe SNFs should not be negatively impacted by the latter. A few commenters stated that the inclusion of contracted nursing staff would lead to inaccurate nursing staff turnover counts. One commenter stated that the inclusion of nursing staff who work solely in an administrative capacity and do not perform direct resident care would lead to inaccurate nursing staff turnover counts. One commenter suggested that CMS delay the implementation of this measure to develop a way to index SNFs to a regional nursing staff turnover measure that would better reflect local labor market variance and factors within a SNF's control.

Response: There is significant research connecting nursing staff turnover with resident outcomes (88 FR 21366). The TEP convened by our contractor concluded that continuity of care is impacted when a caregiver does not work for 60 or more days, regardless of whether they are still employed by the facility or the reason they are no longer employed (on a voluntary or involuntary basis). This was further supported by the analysis we conducted that showed a strong relationship between the Nursing Staff Turnover measure, as proposed, and quality of care.[284] In addition to evidence linking nursing staff turnover to quality, there is also evidence of a significant relationship between directors of nursing and nursing administrator turnover and resident quality of care.

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[278] Zheng, Q, Williams, CS, Shulman, ET, White, AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. J Am Geriatr Soc. 2022; 70(9): 2508–2516.

[279] Zheng Q, Williams CS, Shulman ET, White AJ Association between staff turnover and nursing home quality—evidence from payroll-based journal data. Journal of the American Geriatrics Society. May 2022. doi:10.1111/jgs.17843.

[280] Bostick JE, Rantz MJ, Flesner MK, Riggs CJ Systematic review of studies of staffing and quality in nursing homes. J Am Med Dir Assoc. 2006;7:366–376. *https://pubmed.ncbi.nlm.nih.gov/16843237/.*

[281] Backhaus R, Verbeek H, van Rossum E, Capezuti E, Hamer JPH Nursing staffing impact on quality of care in nursing homes: a systemic review of longitudinal studies. J Am Med Dir Assoc. 2014;15(6):383–393. *https://pubmed.ncbi.nlm.nih.gov/24529872/.*

[282] Spilsbury K., Hewitt C., Stirk L., Bowman C. The relationship between nurse staffing and quality of care in nursing homes: a systematic review. Int J Nurs Stud. 2011; 48(6):732–750. *https://pubmed.ncbi.nlm.nih.gov/21397229/.*

[283] Bostick JE, Rantz MJ, Flesner MK, Riggs CJ. Systematic review of studies of staffing and quality in nursing homes. J Am Med Dir Assoc. 2006;7:366–376. *https://pubmed.ncbi.nlm.nih.gov/16843237/.*

[284] Zheng Q, Williams CS, Shulman ET, White AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. Journal of the American Geriatrics Society. May 2022. doi:10.1111/jgs.17843.

Specifically, retention of directors of nursing and nursing administrators is associated with better resident outcomes and fewer facility health and safety deficiencies.[285] Thus, we believe it is appropriate to include nurses with administrative responsibilities in this measure. We also note that we do not believe delaying this measure to incorporate regional differences is necessary or appropriate at this time. As described previously in this section, this measure went through extensive reliability and validity testing and thus we are confident that this measure, as proposed, is reliable, valid, and an excellent indicator of quality. However, we will continue to assess the measure and if needed, propose measure updates in future rulemaking.

Comment: Many commenters did not support the proposed Nursing Staff Turnover measure because they believe it is unrelated to the intent of the program and reflects circumstances outside of SNFs' control such as market conditions. One commenter stated that the proposed measure is not a good indicator of high-quality care because of current healthcare workforce challenges that are outside the control of SNFs. One commenter believed this measure is solving a problem that does not exist and that current staffing standards are adequate to ensure patient safety. One commenter requested that CMS delay implementing the proposed measure until the nurse staffing minimum standards that the agency is developing are finalized and implemented in long-term care facilities. One commenter noted that the proposed measure will not be risk-adjusted and urged CMS to consider adding risk adjustment to the measure.

Response: We recognize the relationship between nursing staff turnover and quality of care is multi-faceted, but we disagree that this measure is unrelated to the intent of the Program to reward SNFs that provide high quality care. We refer commenters to the proposed rule (88 FR 21366 through 21367) where we discussed several studies that emphasize the evidence of a relationship between nursing staff turnover, quality of care, and patient outcomes. We have selected this measure as a complement to the Total Nursing Staffing measure we finalized in the FY 2023 SNF PPS final rule (87 FR 47576) and as an additional step towards addressing this complex relationship between nurse staffing and quality of care. There are ongoing efforts at CMS to address staffing, including discussions around nurse staffing minimum standards. However, nursing staff minimums and turnover are distinct, and we do not believe those efforts need to be in place prior to finalizing this Nursing Staff Turnover measure for the SNF VBP Program. We reiterate that the proposed Nursing Staff Turnover measure is reliable and valid, and we do not anticipate staffing minimums having significant impact on this proposed measure. Regarding risk-adjustment, as we stated in the proposed rule (88 FR 21368), based on analysis and previous research on turnover measures, and a review by a TEP convened by our contractor, we do not believe the Nursing Staff Turnover measure needs to be risk-adjusted at this time. We do not believe that differences in nursing home turnover rates are related to nursing home acuity. Rather, we believe that turnover is related to management practices such as high-quality leadership, valuing and respecting nursing staff, positive human resource practices, work organization and care practices that help to retain staff and build relationships, and compensation and benefits, among others. It would not be appropriate to have any type of adjustment for these factors; however, we will continue to monitor the data and adjust as needed in future rulemaking.

Comment: Several commenters did not support the proposed measure because SNFs are being impacted by widespread healthcare personnel shortages for which they believe SNFs should not be penalized. A few commenters expressed concern that SNFs do not have the financial support for retention and recruitment and that finalizing this measure could make turnover worse as facilities will be penalized and will then have less money to hire and train additional staff. One commenter suggested CMS instead focus on limiting the number of staffing agencies that are contributing to the staffing crisis. One commenter was concerned that SNFs will have to choose between having enough staff and accepting agency staff at the cost of poor performance on the measure.

Response: We recognize that the past few years, which included the COVID–19 PHE, have significantly affected SNF operations and staffing. We also remain committed to the importance of value-based care and incentivizing quality care tied to payment. SNF staffing, including turnover, is a high priority for us because of its central role in the quality of care for SNF residents. As described previously in this section, the measure specifications were developed based on extensive data analyses, as well as recommendations to us from the project's TEP convened by a CMS contractor. This measure is both a reliable and valid measure of nursing staff turnover as proposed, and therefore, we continue to believe that this measure will provide a more comprehensive assessment of, and accountability for, the quality of care provided to residents despite staffing challenges. Further, this measure, which includes agency staff, has been shown to have a strong relationship with quality of care, and thus we do not believe it is appropriate to revise the measure.[286] We will continue to evaluate the impact on SNFs' behaviors, staffing levels, and quality outcomes as the measure is implemented in the Program.

Comment: One commenter did not support the measure without endorsement by the CBE.

Response: We note the SNF VBP Program is not required to seek endorsement by the CBE to include measures in the Program. We will consider submitting this measure for endorsement by the CBE in the future.

Comment: A few commenters believed the measure is overly complicated. One commenter expressed that the measure will only add to the reporting burden for SNFs.

Response: The Nursing Staff Turnover measure should already be familiar to SNFs that are dually certified as nursing facilities (NFs) because nursing facilities are currently required to report to us the data needed to calculate the measure. We publicly report data on the measure on the Care Compare website *(https://www.medicare.gov/care-compare/)* for the Five-Star Quality Rating System. We chose to align the specifications for the proposed measure with the specifications for the turnover measure being reported by NFs to reduce the reporting burden for SNFs under the SNF VBP.

Comment: One commenter suggested that CMS should collaborate with congressional leaders to provide additional funding to both State and Federal VBP programs instead of offering quality measures that are poorly conceived, like the Nursing Staff Turnover measure.

Response: As noted previously, we believe the Nursing Staff Turnover measure has strong reliability and validity, and the measure was strongly supported in recommendations made by

[285] Bostick JE, Rantz MJ, Flesner MK, Riggs CJ. Systematic review of studies of staffing and quality in nursing homes. J Am Med Dir Assoc. 2006;7:366–376. *https://pubmed.ncbi.nlm.nih.gov/16843237/.*

[286] Zheng Q, Williams CS, Shulman ET, White AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. Journal of the American Geriatrics Society. May 2022. doi:10.1111/jgs.17843.

the TEP convened by CMS contractors. For the SNF VBP Program, the Medicare Payment Advisory Commission (MedPAC) found, according to the 2023 Report to Congress on Medicare Payment Policy, that Medicare payments for SNFs were adequate in the latest year of available data.[287] Additionally, this same report found that a combination of federal policies and the implementation of the new case-mix system resulted in improved financial performance for SNFs, indicating providing additional funding for SNFs unrelated to quality is not appropriate at this time. The goal of this Program is to incentivize high quality care. We believe the addition of the Nursing Staff Turnover measure helps us meet this goal because the measure displays a strong relationship to quality.[288]

Comment: One commenter requested CMS amend the PBJ data submission policies to allow facilities to submit payroll data used to calculate the Nursing Staff Turnover measure after the submission deadline to allow SNFs to provide the most complete and accurate staffing data for consumers.

Response: We thank the commenter for their suggestion. This request would be a considerable update to our current policies around data submission that impacts programs beyond the SNF VBP Program. However, we will take it into consideration for future rulemaking.

After consideration of public comments, we are finalizing adoption of the Total Nursing Staff Turnover measure beginning with the FY 2026 SNF VBP program year.

c. Adoption of the Percent of Residents Experiencing One or More Falls With Major Injury (Long-Stay) Measure Beginning With the FY 2027 SNF VBP Program Year

We proposed to adopt the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) Measure (''Falls with Major Injury (Long-Stay) measure'') beginning with the FY 2027 SNF VBP program year. The Falls with Major Injury (Long-Stay) measure is an outcome measure that estimates the percentage of long-stay residents who have experienced one or more falls with major injury. We refer readers to the specifications for this measure, which are located in the Minimum Data Set (MDS) 3.0 Quality Measures User's Manual Version 15 available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqiqualitymeasures.* The Falls with Major Injury (Long-Stay) measure was endorsed by the consensus-based entity (CBE) in 2011. The measure is currently reported by nursing facilities under the CMS Nursing Home Quality Initiative (NHQI) and the Five-Star Quality Rating System and those results are publicly reported on the Care Compare website, available at *https://www.medicare.gov/care-compare/.*

(1) Background

Falls are the leading cause of injury-related death among persons aged 65 years and older. According to the Centers for Disease Control and Prevention (CDC), approximately one in four adults aged 65 years and older fall each year, and fall-related emergency department visits are estimated at approximately 3 million per year.[289] In 2016, nearly 30,000 U.S. residents aged 65 years and older died as the result of a fall, resulting in an age-adjusted mortality rate of 61.6 deaths per 100,000 people. This represents a greater than 30 percent increase in fall-related deaths from 2007, where the age-adjusted mortality rate was 47.0 deaths per 100,000 people.[290] Additionally, the death rate from falls was higher among adults aged 85 years and older as indicated by a mortality rate of 257.9 deaths per 100,000 people.[291]

Of the 1.6 million residents in U.S. nursing facilities, approximately half fall annually, with one in three having two or more falls in a year. One in every ten residents who falls has a serious related injury, and about 65,000 residents suffer a hip fracture each year.[292] An analysis of MDS data from FY 2019 Q2 found that, among the 14,586 nursing facilities included in the sample, the percent of long-stay residents who experienced one or more falls with major injury ranged from zero percent to nearly 21 percent. This wide variation in facility-level fall rates indicates a performance gap and suggests that there are opportunities to improve performance on this measure.

It is important to monitor injurious falls among the long-stay population because of the potentially negative impacts on resident health outcomes and quality of life. Research has found that injurious falls are one of the leading causes of disability and death for all nursing home residents. Specifically, falls have serious health consequences, such as reduced quality of life, decreased functional abilities, anxiety and depression, serious injuries, and increased risk of morbidity and mortality.[293] [294]

Injurious falls are also a significant cost burden to the entire healthcare system. The U.S. spends approximately $50 billion on medical costs related to non-fatal fall-related injuries and $754 million on medical costs related to fatal falls annually.[295] Of the amount paid on non-fatal fall injuries, Medicare pays approximately $29 billion, while private or out-of-pocket payers pay $12 billion. Research suggests that acute care costs incurred for falls among nursing home residents range from $979 for a typical case with a simple fracture to $14,716 for a typical case with multiple injuries.[296] Other research examining hospitalizations of nursing home residents with serious fall-related injuries (intracranial bleed, hip fracture, or other fracture) found an average cost of $23,723.[297]

Research has found that 78 percent of falls are anticipated physiologic falls, which are defined as falls among individuals who scored high on a risk assessment scale, meaning their risk could have been identified in advance of the fall.[298] To date, studies have

[287] MedPAC, 2023 *https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf.*

[288] Zheng Q, Williams CS, Shulman ET, White AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. Journal of the American Geriatrics Society. May 2022. doi:10.1111/jgs.17843.

[289] Burns E, Kakara R. Deaths from Falls Among Persons Aged ≥65 Years—United States, 2007–2016. *MMWR Morb Mortal Wkly Rep* 2018;67:509–514. DOI: *http://dx.doi.org/10.15585/mmwr.mm6718a1.*

[290] Ibid.

[291] Ibid.

[292] The Falls Management Program: A Quality Improvement Initiative for Nursing Facilities: Chapter 1. introduction and program overview. Agency for Healthcare Research and Quality. *https://www.ahrq.gov/patient-safety/settings/long-term-care/resource/injuries/fallspx/man1.html.* Published December 2017. Accessed December 13, 2022.

[293] The Falls Management Program: A Quality Improvement Initiative for Nursing Facilities: Chapter 1. Introduction and Program Overview. Agency for Healthcare Research and Quality. *https://www.ahrq.gov/patient-safety/settings/long-term-care/resource/injuries/fallspx/man1.html.* Published December 2017. Accessed December 13, 2022.

[294] Bastami M, Azadi A. Effects of a Multicomponent Program on Fall Incidence, Fear of Falling, and Quality of Life among Older Adult Nursing Home Residents. *Ann Geriatr Med Res.* 2020;24(4):252–258. doi:10.4235/agmr.20.0044.

[295] Cost of older adult falls. Centers for Disease Control and Prevention. *https://www.cdc.gov/falls/data/fall-cost.html.* Published July 9, 2020. Accessed December 13, 2022.

[296] Sorensen SV, de Lissovoy G, Kunaprayoon D, Resnick B, Rupnow MF, Studenski S. A taxonomy and economic consequence of nursing home falls. *Drugs Aging.* 2006;23(3):251–62.

[297] Quigley PA, Campbell RR, Bulat T, Olney RL, Buerhaus P, Needleman J. Incidence and cost of serious fall-related injuries in nursing homes. *Clin Nurs Res.* Feb 2012;21(1):10–23.

[298] Morse, J.M. Enhancing the safety of hospitalization by reducing patient falls. *Am J Infect Control* 2002; 30(6): 376–80.

identified a number of risk factors for falls within the long-stay population, including impaired cognitive function, history of falls, difficulties with walking and balancing, vitamin D deficiency, and use of psychotropic medications.[299] [300] [301] In addition, residents who experience dementia or depression, are underweight, or are over the age of 85 are at a higher risk of falling.[302] [303] [304] While much of this research has been conducted in long-term care facilities or nursing homes, we believe this research is relevant to the SNF setting, because approximately 94 percent of long-term care facilities are dually certified as both SNFs and nursing facilities (86 FR 42508). Therefore, these risk factors described above suggest that SNFs may be able to identify, reduce, and prevent the incidence of falls among their residents.[305] [306] [307] [308]

Given the effects of falls with major injury, preventing and reducing their occurrence in SNFs is critical to delivering safe and high-quality care. We believe the Falls with Major Injury (Long-Stay) measure aligns with this goal by monitoring the occurrence of falls with major injury and assessing SNFs on their performance on fall prevention efforts. In doing so, we believe this measure will promote patient safety and increase the transparency of care quality in the SNF setting, and it will align the Program with the Patient Safety domain of CMS' Meaningful Measures 2.0 Framework.[309]

We believe there are effective interventions that SNFs can implement to reduce and prevent falls, including those that cause major injury. Specifically, several studies observed that multifactorial interventions such as exercise, medication review, risk assessment, vision assessment, and environmental assessment significantly reduce fall rates.[310] [311] [312] Another study found that a single intervention of exercise reduced the number of resident falls in the nursing home setting by 36 percent and the number of recurrent fallers by 41 percent.[313] Additionally, various systematic reviews link facility structural characteristics to falls with major injury. For example, the incorporation of adequate equipment throughout the facility, such as hip protectors or equipment used for staff education tasks, may reduce fall rates or fall-related injuries.[314] [315] In addition, poor communication between staff, inadequate staffing levels, and limited facility equipment have been identified as barriers to implementing fall prevention programs in facilities.[316] Other studies have shown that proper staff education can significantly reduce fall rates.[317] [318] The effectiveness of these interventions suggest improvement of fall rates among SNF residents is possible through modification of provider-led processes and interventions, which supports the overall goal of the SNF VBP Program.

(2) Overview of Measure

The Falls with Major Injury (Long-Stay) measure is an outcome measure that reports the percentage of long-stay residents in a nursing home who have experienced one or more falls with major injury using 1 year of data from the Minimum Data Set (MDS) 3.0. This measure defines major injuries as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematomas. Long-stay residents are defined as residents who have received 101 or more cumulative days of nursing home care by the end of the measure reporting period (performance period). This measure is a patient safety measure reported at the facility-level.

Although the Falls with Major Injury (Long-Stay) measure is a long-stay measure, we believe that including a long-stay measure in the SNF VBP Program is appropriate because it will better capture the quality of care provided to the entirety of the population that resides in facilities that are dually certified as SNFs and nursing facilities, including long-stay residents who continue to receive Medicare coverage for certain services provided

[299] Cost of older adult falls. Centers for Disease Control and Prevention. *https://www.cdc.gov/falls/data/fall-cost.html.* Published July 9, 2020. Accessed December 13, 2022.

[300] Galik, E., Resnick, B., Hammersla, M., & Brightwater, J. (2014). Optimizing function and physical activity among nursing home residents with dementia: testing the impact of function-focused care. *Gerontologist* 54(6), 930–943. *https://doi.org/10.1093/geront/gnt108.*

[301] Broe KE, Chen TC, Weinberg J, Bischoff-Ferrari HA, Holick MF, Kiel DP. A higher dose of vitamin d reduces the risk of falls in nursing home residents: a randomized, multiple-dose study. *J Am Geriatr Soc.* 2007;55(2):234–239. doi:10.1111/j.1532–5415.2007.01048.x.

[302] Zhang N, Lu SF, Zhou Y, Zhang B, Copeland L, Gurwitz JH. Body Mass Index, Falls, and Hip Fractures Among Nursing Home Residents. *J Gerontol A Biol Sci Med Sci.* 2018;73(10):1403–1409. doi:10.1093/gerona/gly039.

[303] Fernando E, Fraser M, Hendriksen J, Kim CH, Muir-Hunter SW. Risk Factors Associated with Falls in Older Adults with Dementia: A Systematic Review. *Physiother Can.* 2017;69(2):161–170. doi:10.3138/ptc.2016–14.

[304] Grundstrom AC, Guse CE, Layde PM. Risk factors for falls and fall-related injuries in adults 85 years of age and older. *Arch Gerontol Geriatr.* 2012;54(3):421–428. doi:10.1016/j.archger.2011.06.008.

[305] Morris JN, Moore T, Jones R, et al. Validation of long-term and post-acute care quality indicators. CMS Contract No: 500–95–0062.

[306] Chen XL, Liu YH, Chan DK, Shen Q, Van Nguyen H. Chin Med J (Engl). Characteristics associated with falls among the elderly within aged care wards in a tertiary hospital: A Retrospective. 2010 Jul; 123(13):1668–72.

[307] Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. J Clin Nurs. 2008 Jan; 17(1):126–34.

[308] Lee JE, Stokic DS. Risk factors for falls during inpatient rehabilitation. Am J Phys Med Rehabil. 2008 May; 87(5):341–50; quiz 351, 422.

[309] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[310] Gulka, H.J., Patel, V., Arora, T., McArthur, C., & Iaboni, A. (2020). Efficacy and generalizability of falls prevention interventions in nursing homes: A systematic review and meta-analysis. *Journal of the American Medical Directors Association,* 21(8), P1024–1035.E4. *https://doi.org/10.1016/j.jamda.2019.11.012.*

[311] Tricco, A.C., Thomas, S. M., Veroniki, A.A., Hamid, J.S., Cogo, E., Strifler, L., Khan, P.A., Robson, R., Sibley, K.M., MacDonald, H., Riva, J.J., Thavorn, K., Wilson, C., Holroyd-Leduc, J., Kerr, G.D., Feldman, F., Majumdar, S.R., Jaglal, S.B., Hui, W., & Straus, S.E. (2017). Comparisons of interventions for preventing falls in older adults: A systematic review and meta-analysis. *Journal of the American Medical Association,* 318(17), 1687–1699. *https://doi.org/10.1001/jama.2017.15006.*

[312] Vlaeyen, E., Coussement, J., Leysens, G., Van der Elst, E., Delbaere, K., Cambier, D., Denhaerynck, K., Goemaere, S., Wertelaers, A., Dobbels, F., Dejaeger, E., & Milisen, K. (2015). Characteristics and effectiveness of fall prevention programs in nursing homes: A systematic review and meta-analysis of randomized control trials. *Journal of the American Geriatrics Society,* 6(3), 211–21. *https://doi.org/10.1111/jgs.13254.*

[313] Gulka, H.J., Patel, V., Arora, T., McArthur, C., & Iaboni, A. (2020). Efficacy and generalizability of falls prevention interventions in nursing homes: A systematic review and meta-analysis. *Journal of the American Medical Directors Association,* 21(8), P1024–1035.E4. *https://doi.org/10.1016/j.jamda.2019.11.012.*

[314] Crandall, M., Duncan, T., Mallat, A., Greene, W., Violano, P., & Christmas, B. (2016). Prevention of fall-related injuries in the elderly: An eastern association for the surgery of trauma practice management guideline. *Journal of Trauma and Acute Care Surgery,* 81(1), 196–206. *https://doi.org/10.1097/TA.0000000000001025.*

[315] Vlaeyen, E., Stas, J., Leysens, G., Van der Elst, E., Janssens, E., Dejaeger, E., Dobbels, F., & Milisen, K. (2017). Implementation of fall prevention in residential care facilities: A systematic review of barriers and facilitators. *International Journal of Nursing Studies,* 70, 110–121. *https://doi.org/10.1016/j.ijnurstu.2017.02.002.*

[316] Ibid.

[317] Gulka, H.J., Patel, V., Arora, T., McArthur, C., & Iaboni, A. (2020). Efficacy and generalizability of falls prevention interventions in nursing homes: A systematic review and meta-analysis. *Journal of the American Medical Directors Association,* 21(8), P1024–1035.E4. *https://doi.org/10.1016/j.jamda.2019.11.012.*

[318] Tricco, A.C., Thomas, S.M., Veroniki, A.A., Hamid, J.S., Cogo, E., Strifler, L., Khan, P.A., Robson, R., Sibley, K.M., MacDonald, H., Riva, J.J., Thavorn, K., Wilson, C., Holroyd-Leduc, J., Kerr, G.D., Feldman, F., Majumdar, S.R., Jaglal, S.B., Hui, W., & Straus, S.E. (2017). Comparisons of interventions for preventing falls in older adults: A systematic review and meta-analysis. *Journal of the American Medical Association,* 318(17), 1687–1699. *https://doi.org/10.1001/jama.2017.15006.*

by nursing facilities. We discussed the potential to include long -stay measures in the SNF VBP Program in the FY 2022 SNF PPS final rule Summary of Comments Received on Potential Future Measures for the SNF VBP Program (86 FR 42507 through 42510). Specifically, we stated that the majority of long-stay residents are Medicare beneficiaries, regardless of whether they are in a Medicare Part A SNF stay, because they are enrolled in Medicare Part B and receive Medicare coverage of certain services provided by long-term care facilities even if they are a long-stay resident. We did not receive any negative comments on inclusion of this specific Falls with Major Injury (Long-Stay) measure or long-stay measures generally in the Program in response to this request for comment.

We have adopted a similar measure in the SNF QRP, the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 46440 through 46444), but that measure excludes long-stay residents. We believe it is important to hold SNFs accountable for the quality of care provided to long-stay residents given that the majority of long-term care facilities are dually certified as SNFs and nursing facilities. Additionally, we believe the Falls with Major Injury (Long-Stay) measure satisfies the requirement to consider and apply, as appropriate, quality measures specified under section 1899B(c)(1) of the Act, in which this measure aligns with the domain, incidence of major falls, described at section 1899B(c)(1)(D) of the Act. Therefore, we believe it is appropriate for the SNF VBP program to include a falls with major injury for long-stay resident measure.

Testing for this measure has demonstrated that the Falls with Major Injury (Long-Stay) measure has sufficient reliability and validity. For example, signal-to-noise and split-half reliability analyses found that the measure exhibited moderate reliability. Validity testing showed that there are meaningful differences in nursing facility-level scores for this measure, indicating good validity. For additional details on measure testing, we refer readers to the MAP PAC/LTC: 2022–2023 MUC Cycle Measure Specifications Manual available at *https://mmshub.cms.gov/sites/default/files/map-pac-muc-measure-specifications-2022-2023.pdf.*

(a) Interested Parties and TEP Input

In considering the selection of this measure for the SNF VBP Program, CMS convened a TEP in March 2022 which focused on the identification of measurement gaps and measure development priorities for the Program. Panelists were largely supportive of including a falls with major injury measure compared to a general falls measure or a falls with injury measure for several reasons including: (1) the broad definition of falls; and (2) the consensus-based entity endorsement of the Falls with Major Injury (Long-Stay) measure in the Nursing Home Quality Initiative Program. A summary of the TEP meeting is available at *https://mmshub.cms.gov/sites/default/files/SNF-VBP-TEP-Summary-Report-Mar2022.pdf.*

(b) Measure Applications Partnership (MAP) Review

We included the Falls with Major Injury (Long-Stay) measure as a SNF VBP measure under consideration in the publicly available ''2022 Measures Under Consideration List''.[319] The MAP supported the Falls with Major Injury (Long-Stay) measure for rulemaking, noting that the measure would add value to the Program because of the lack of an existing falls measure and that it would help improve patient safety. We refer readers to the final 2022–2023 MAP recommendations available at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

(3) Data Sources

The Falls with Major Injury (Long-Stay) measure is calculated using 1 year of resident data collected through the MDS. The collection instrument is the Resident Assessment Instrument (RAI), which contains the MDS 3.0. The RAI is a tool used by nursing home staff to collect information on residents' strengths and needs. We describe the measure specifications in more detail below and also refer readers to the MDS 3.0 Quality Measures User's Manual Version 15.0 for further details on how these data components are utilized in calculating the Falls with Major Injury (Long-Stay) measure available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqiqualitymeasures.* Technical information for the MDS 3.0 is also available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.* The Falls with Major Injury (Long-Stay) measure is calculated using data from the MDS, which all Medicare-certified SNFs and Medicaid-certified nursing facilities are currently required to report. Therefore, this measure will not impose any additional data collection or submission burden for SNFs.

(4) Measure Specifications

(a) Denominator

All long-stay residents with one or more look-back scan assessments no more than 275 days prior to the target assessment, except those that meet the exclusion criteria, are included in the measure denominator. Long-stay residents are defined as those who have 101 or more cumulative days of nursing home care by the end of the measure reporting period (performance period). Residents who return to the nursing home following a hospital discharge would not have their cumulative days in the facility reset to zero, meaning that days of care from a previous admission will be added to any subsequent admissions.

The MDS includes a series of assessments and tracking documents, such as Omnibus Budget Reconciliation Act (OBRA) Comprehensive Assessments, OBRA Quarterly Assessments, OBRA Discharge Assessments or PPS assessments. For the purposes of this measure, a target assessment, which presents the resident's status at the end of the episode of care or their latest status if their episode of care is ongoing, is selected for each long-stay resident. Target assessments may be an Omnibus Budget Reconciliation Act (OBRA) admission, quarterly, annual, or significant change/correction assessment; or PPS 5-day assessments; or discharge assessment with or without anticipated return. For more information on how we define target assessments, we refer readers to the MDS 3.0 Quality Measures User's Manual Version 15.0 available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqiqualitymeasures.*

(b) Denominator Exclusions

Residents are excluded from the denominator if the number of falls with major injury was not coded for all of the look-back scan assessments. A SNF will not be scored on this measure if it does not have long-stay residents, or residents with 101 or more cumulative days of care. The measure also excludes all SNF swing beds because they do not provide care to long-stay residents.

[319] 2022 Measures Under Consideration Spreadsheet available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

(c) Numerator

The measure numerator includes long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury. Major injuries include bone fractures, joint dislocations, closed-head injuries with altered consciousness, or subdural hematomas. The selection period for the look-back scan consists of the target assessment and all qualifying earlier assessments in the scan.

An assessment should be included in the scan if it meets all of the following conditions: (1) it is contained within the resident's episode, (2) it has a qualifying Reason for Assessment (RFA), (3) its target date is on or before the target date for the target assessment, and (4) its target date is no more than 275 days prior to the target date of the target assessment. For the purposes of this measure, we defined the target date as the event date of an MDS record (that is, entry date for an entry record or discharge date for a discharge record or death-in-facility record) or the assessment reference date (for all records that are not entry, discharge, or death-in-facility). For additional target date details, we refer readers to Chapter 1 of the MDS 3.0 Quality Measures User's Manual Version 15.0 available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqiqualitymeasures.*

A 275-day time period is used to include up to three quarterly OBRA assessments. The earliest of these assessments would have a look-back period of up to 93 days, which would cover a total of about 1 year. To calculate the measure, we scan these target assessments and any qualifying earlier assessments described in the previous paragraph for indicators of falls with major injury.

(5) Risk Adjustment

The Falls with Major Injury (Long-Stay) measure is not risk-adjusted. We considered risk adjustment during measure development, and we tested various risk-adjustment models, but none had sufficient predictive ability.

(6) Measure Calculation

The Falls with Major Injury (Long-Stay) measure is calculated and reported at the facility level. Specifically, to calculate the measure score, we proposed to first determine the measure denominator by identifying the total number of long-stay residents with a qualifying target assessment (OBRA, PPS, or discharge), one or more look-back scan assessments, and who do not meet the exclusion criteria. Using that set of residents, we calculate the numerator by identifying the total number of those residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury. We then divide the numerator by the denominator and multiply the resulting ratio by 100 to obtain the percentage of long-stay residents who experience one or more falls with major injury. A lower measure rate indicates better performance on the measure. For additional details on the calculation method, we refer readers to the specifications for the Falls with Major Injury (Long-Stay) measure included in the MDS 3.0 Quality Measures User's Manual available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqiqualitymeasures.*

We solicited public comment on our proposal to adopt the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) measure beginning with the FY 2027 SNF VBP program year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the proposed Falls with Major Injury (Long-Stay) measure.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concerns about the proposed measure. One commenter did not believe that MDS data were sufficiently valid for the SNF VBP program without an auditing program. One commenter expressed concern that the measure is not risk-adjusted. Another commenter was uncertain about the measure's use in the SNF VBP Program because it has not been adopted in the SNF QRP. One commenter did not believe that measures of long-stay residents' care were appropriate for the Program. Another commenter worried that facilities may restrict residents' movements to avoid falls and injuries, which would reduce residents' quality of life and affect their physical strength, balance, and flexibility.

Response: We thank the commenters for this feedback. We proposed to adopt a validation process for SNF VBP measures that are calculated using MDS data and refer readers to section VIII.G.4. of this final rule for additional details regarding that proposal, which we are finalizing, as well as our responses to comments on it.

We appreciate the commenter's concern about risk adjustment. As we explained in the proposed rule (88 FR 21371), we tested risk-adjustment models for this measure but found that none had sufficient predictive ability. Injurious falls are one of the leading causes of disability and death for all nursing home residents, and falls have serious health consequences, such as reduced quality of life, decreased functional abilities, anxiety and depression, serious injuries, and increased risk of morbidity and mortality.[320] [321] Based on these risks, we continue to believe that the measure is appropriate for adoption in the SNF VBP Program as part of our ongoing efforts to ensure nursing home residents' safety in that care setting. We will continue assessing the feasibility of risk-adjustment for this measure in the future.

We proposed to adopt this measure in the SNF VBP Program because falls represent a significant risk to nursing home residents. We believe that the SNF VBP Program's structure will provide strong incentives for SNFs to protect residents from those falls. We further note that, as we discussed in the proposed rule (88 FR 21370), we have adopted a similar measure for the SNF QRP. We also explained our reasoning for applying measures of long-stay residents' care in the proposed rule (88 FR 21370), where we stated that we believe long-stay measures better capture the quality of care provided to the entirety of the population residing in facilities that are dually certified as SNFs and nursing facilities. Even though Medicare Part A does not cover nursing facility stays, long-stay residents who are enrolled in Medicare Part B can still obtain Medicare Part B coverage of certain services, such as physical therapy, that are provided by nursing facilities.

Finally, while we agree with the commenter that no facility should restrict residents' movement to maximize its performance on this measure, we do not believe that

[320] The Falls Management Program: A Quality Improvement Initiative for Nursing Facilities: Chapter 1. Introduction and Program Overview. Agency for Healthcare Research and Quality. *https://www.ahrq.gov/patient-safety/settings/longterm-care/resource/injuries/fallspx/man1.html.* Published December 2017. Accessed December 13, 2022.

[321] Bastami M, Azadi A. Effects of a Multicomponent Program on Fall Incidence, Fear of Falling, and Quality of Life among Older Adult Nursing Home Residents. *Ann Geriatr Med Res.* 2020;24(4):252–258. doi:10.4235/agmr.20.0044.

facilities will violate their duties to their residents' care and safety in such a manner. We believe that facilities will take appropriate steps to protect their residents from injurious falls while providing them with the support they need to maintain mobility, physical strength, balance, and flexibility. We further add that we are also adopting the DC Function measure, in which facilities must improve their resident function from admission to perform well on the measure which may reduce the incentive to restrict patient movements. We will monitor performance on the measure as well as potential unintended consequences carefully.

Comment: One commenter suggested that CMS monitor all injurious falls based on the risk of injury associated with them. The commenter also suggested that CMS adopt requirements for SNFs to develop protective interventions to protect residents from injury. Another commenter urged CMS to require Medicare Advantage (MA) plans to report falls data. One commenter suggested that CMS consider providing positive incentives for SNFs to encourage them to create falls management programs and protocols. One commenter expressed concern about the risk of facilities cherry-picking residents to avoid poor performance on this measure.

Response: We have not developed a measure of all falls for the SNF VBP Program at this time, nor are we aware of other measure developers having developed that type of measure. We will consider whether such a measure is appropriate for the Program in the future. We intend to work with Quality Improvement Organizations (QIOs) to promote safety initiatives in the nursing facility setting. Further, while we do not currently incorporate a measure of falls in our Star Ratings system for MA plans, we will consider whether such a measure would be appropriate in the future.

We note that patient safety is both one of the measure categories described at section 1888(h)(2)(A)(ii) and that prevention of falls specifically is a patient safety issue and one of the agency's priorities. We believe the positive incentives provided by the Program, including the policy changes we have proposed this year related to the Health Equity Adjustment and increase in payback percentage, provide strong incentives for SNFs to design and implement safety protocols, including falls management.

We share the commenter's concern about facilities' potentially cherry-picking residents to avoid poor performance on this measure and will monitor performance and any unintended consequences carefully.

Comment: Several commenters opposed the proposal to adopt the Falls with Major Injury (Long-Stay) measure. Some commenters were concerned that MDS data are not sufficiently accurate for quality measurement and suggested that CMS adopt a claims-based measure of falls instead. One commenter believed that the measure does not align with the SNF VBP Program's intent to link FFS reimbursement with care and outcomes of FFS beneficiaries. Another commenter opposed the measure's adoption based on population differences and suggested that CMS adopt the SNF QRP's Falls with Major Injury instead, which they stated is better aligned with Part A reimbursements affected by the SNF VBP Program. One commenter opposed the measure because it is already publicly reported and available to consumers.

Response: We appreciate the commenters' concerns. As explained below, we are finalizing a proposal to validate the MDS data used to calculate SNF VBP measures, and we believe that this policy will help to ensure that those data are accurate for quality purposes.

We disagree with the commenter's assertion that this measure does not align with the SNF VBP Program's intent. As we described in the proposed rule (88 FR 21370), we believe that this measure better captures the quality of care provided to the entirety of the population that resides in facilities that are dually certified as SNFs and nursing facilities, including long-stay residents who continue to receive Medicare coverage for certain services provided by nursing facilities. While we considered the SNF QRP's measure on a similar topic, we noted in the proposed rule that the SNF QRP's measure excludes long-stay residents and that we believe it is important to hold SNFs accountable for the quality of care they provide to long-stay residents since the majority of long-term care facilities are dually certified as SNFs and nursing facilities.

Finally, we agree with the commenter's reasoning that public reporting of quality data is an important feature of quality programs. We continue to believe, however, that providing financial incentives for quality performance through our pay-for-performance programs takes the next step beyond public reporting and provides direct incentives for quality improvement in clinical care.

After consideration of public comments, we are finalizing adoption of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) measure beginning with the FY 2027 SNF VBP program year.

d. Adoption of the Discharge Function Score Measure Beginning With the FY 2027 SNF VBP Program Year

We proposed to adopt the Discharge Function Score (''DC Function'') measure beginning with the FY 2027 SNF VBP Program.[322] We also proposed to adopt this measure in the SNF QRP (see section VII. of this final rule).

(1) Background

Maintenance or improvement of physical function among older adults is increasingly an important focus of healthcare. Adults aged 65 years and older constitute the most rapidly growing population in the United States, and functional capacity in physical (non-psychological) domains has been shown to decline with age.[323] Moreover, impaired functional capacity is associated with poorer quality of life and an increased risk of all-cause mortality, postoperative complications, and cognitive impairment, the latter of which can complicate the return of a resident to the community from post-acute care.[324] [325] [326] Nonetheless, evidence suggests that physical

[322] This measure was submitted to the Measure Under Consideration (MUC) List as the Cross-Setting Discharge Function Score. Subsequent to the MAP workgroup meetings, the measure developer modified the name.

[323] High KP, Zieman S, Gurwitz J, Hill C, Lai J, Robinson T, Schonberg M, Whitson H. Use of Functional Assessment to Define Therapeutic Goals and Treatment. J Am Geriatr Soc. 2019 Sep;67(9):1782–1790. doi: 10.1111/jgs.15975. Epub 2019 May 13. PMID: 31081938; PMCID: PMC6955596.

[324] Clouston SA, Brewster P, Kuh D, Richards M, Cooper R, Hardy R, Rubin MS, Hofer SM. The dynamic relationship between physical function and cognition in longitudinal aging cohorts. Epidemiol Rev. 2013;35(1):33–50. doi: 10.1093/epirev/mxs004. Epub 2013 Jan 24. PMID: 23349427; PMCID: PMC3578448.

[325] Michael YL, Colditz GA, Coakley E, Kawachi I. Health behaviors, social networks, and healthy aging: cross-sectional evidence from the Nurses' Health Study. Qual Life Res. 1999 Dec;8(8):711–22. doi: 10.1023/a:1008949428041. PMID: 10855345.

[326] High KP, Zieman S, Gurwitz J, Hill C, Lai J, Robinson T, Schonberg M, Whitson H. Use of Functional Assessment to Define Therapeutic Goals and Treatment. J Am Geriatr Soc. 2019 Sep;67(9):1782–1790. doi: 10.1111/jgs.15975. Epub 2019 May 13. PMID: 31081938; PMCID: PMC6955596.

functional abilities, including mobility and self-care, are modifiable predictors of resident outcomes across PAC settings, including functional recovery or decline after post-acute care,[327] [328] [329] [330] [331] rehospitalization rates,[332] [333] [334] discharge to community,[335] [336] and falls.[337] Because evidence shows that older adults experience aging heterogeneously and require individualized and comprehensive healthcare, functional status can serve as a vital component in informing the provision of healthcare and thus indicate a SNF's quality of care.[338] [339]

As stated in section VII. of this final rule, we proposed this measure for the SNF QRP, and we also proposed it for adoption in the SNF VBP Program under section 1888(h)(2)(A)(ii) of the Act. We believe it is important to measure quality across the full range of outcomes for Medicare beneficiaries during a SNF stay. Further, adoption of this measure will ensure that the SNF VBP Program's measure set aligns with the Person-Centered Care domain of CMS' Meaningful Measures 2.0 Framework.

We included the DC Function measure on the 2022–2023 MUC list for the Inpatient Rehabilitation Facility QRP, Home Health QRP, Long Term Care Hospital QRP, SNF QRP, and SNF VBP Program. While the DC Function measure is not yet implemented in the SNF QRP or other PAC programs, SNFs already report many of the elements that will be used to calculate this measure.[340] As such, we believe SNFs have had sufficient time to ensure successful reporting of the data elements needed for this measure.

(2) Overview of Measure

The DC Function measure is an outcome measure that estimates the percentage of SNF residents who meet or exceed an expected discharge score during the reporting period. The DC Function measure's numerator is the number of SNF stays with an observed discharge function score that is equal to or higher than the calculated expected discharge function score. The observed discharge function score is the sum of individual function items at discharge. The expected discharge function score is computed by risk adjusting the observed discharge function score for each SNF stay. Risk adjustment controls for resident characteristics, such as admission function score, age, and clinical conditions. The denominator is the total number of SNF stays with a MDS record in the measure target period (four rolling quarters) which do not meet the measure exclusion criteria. For additional details regarding the numerator, denominator, risk adjustment, and exclusion criteria, we refer readers to the *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report.*[341]

The DC Function measure implements a statistical imputation approach for handling ''missing'' standardized functional assessment data elements. The coding guidance for standardized functional assessment data elements allows for using ''Activity Not Attempted'' (ANA) codes, resulting in ''missing'' information about a patient's functional ability on at least some items, at admission and/or discharge, for a substantive portion of SNF patients. Currently, functional outcome measures in the SNF QRP use a simple imputation method whereby all ANA codes or otherwise missing scores, on both admission and discharge records, are recoded to ''1'' or ''most dependent.'' Statistical imputation, on the other hand, replaces these missing values for a variable based on the values of other, non-missing variables in the data and which are otherwise similar to the assessment with a missing value. Specifically, the DC Function measure's statistical imputation allows missing values (for example, the ANA codes) to be replaced with any value from 1 to 6, based on a patient's clinical characteristics and codes assigned on other standardized functional assessment data elements. The measure implements separate imputation models for each standardized functional assessment data elements used in measure construction at admission and discharge. Relative to the current simple imputation method, this statistical imputation approach increases the precision and accuracy and reduces the bias in estimates for missing item scores. We refer readers to the *Discharge Function Score for Skilled Nursing*

[327] Deutsch A, Palmer L, Vaughan M, Schwartz C, McMullen T. Inpatient Rehabilitation Facility Patients' Functional Abilities and Validity Evaluation of the Standardized Self-Care and Mobility Data Elements. Arch Phys Med Rehabil. 2022 Feb 11:S0003–9993(22)00205–2. doi: 10.1016/j.apmr.2022.01.147. Epub ahead of print. PMID: 35157893.

[328] Hong I, Goodwin JS, Reistetter TA, Kuo YF, Mallinson T, Karmarkar A, Lin YL, Ottenbacher KJ. Comparison of Functional Status Improvements Among Patients With Stroke Receiving Postacute Care in Inpatient Rehabilitation vs Skilled Nursing Facilities. JAMA Netw Open. 2019 Dec 2;2(12):e1916646. doi: 10.1001/jamanetworkopen.2019.16646. PMID: 31800069; PMCID: PMC6902754.

[329] Alcusky M, Ulbricht CM, Lapane KL. Postacute Care Setting, Facility Characteristics, and Poststroke Outcomes: A Systematic Review. Arch Phys Med Rehabil. 2018;99(6):1124–1140.e9. doi:10.1016/j.apmr.2017.09.005. PMID: 28965738; PMCID: PMC5874162.

[330] Chu CH, Quan AML, McGilton KS. Depression and Functional Mobility Decline in Long Term Care Home Residents with Dementia: a Prospective Cohort Study. Can Geriatr J. 2021;24(4):325–331. doi:10.5770/cgj.24.511. PMID: 34912487; PMCID: PMC8629506.

[331] Lane NE, Stukel TA, Boyd CM, Wodchis WP. Long-Term Care Residents' Geriatric Syndromes at Admission and Disablement Over Time: An Observational Cohort Study. J Gerontol A Biol Sci Med Sci. 2019;74(6):917–923. doi:10.1093/gerona/gly151. PMID: 29955879; PMCID: PMC6521919.

[332] Li CY, Haas A, Pritchard KT, Karmarkar A, Kuo YF, Hreha K, Ottenbacher KJ. Functional Status Across Post-Acute Settings is Associated With 30-Day and 90-Day Hospital Readmissions. J Am Med Dir Assoc. 2021 Dec;22(12):2447–2453.e5. doi: 10.1016/j.jamda.2021.07.039. Epub 2021 Aug 30. PMID: 34473961; PMCID: PMC8627458.

[333] Middleton A, Graham JE, Lin YL, Goodwin JS, Bettger JP, Deutsch A, Ottenbacher KJ. Motor and Cognitive Functional Status Are Associated with 30-day Unplanned Rehospitalization Following Post-Acute Care in Medicare Fee-for-Service Beneficiaries. J Gen Intern Med. 2016 Dec;31(12):1427–1434. doi: 10.1007/s11606–016–3704–4. Epub 2016 Jul 20. PMID: 27439979; PMCID: PMC5130938.

[334] Gustavson AM, Malone DJ, Boxer RS, Forster JE, Stevens-Lapsley JE. Application of High-Intensity Functional Resistance Training in a Skilled Nursing Facility: An Implementation Study. Phys Ther. 2020;100(10):1746–1758. doi: 10.1093/ptj/pzaa126. PMID: 32750132; PMCID: PMC7530575.

[335] Minor M, Jaywant A, Toglia J, Campo M, O'Dell MW. Discharge Rehabilitation Measures Predict Activity Limitations in Patients with Stroke Six Months after Inpatient Rehabilitation. Am J Phys Med Rehabil. 2021 Oct 20. doi: 10.1097/PHM.0000000000001908. Epub ahead of print. PMID: 34686630.

[336] Dubin R, Veith JM, Grippi MA, McPeake J, Harhay MO, Mikkelsen ME. Functional Outcomes, Goals, and Goal Attainment among Chronically Critically Ill Long-Term Acute Care Hospital Patients. Ann Am Thorac Soc. 2021;18(12):2041–2048. doi:10.1513/AnnalsATS.202011–1412OC. PMID: 33984248; PMCID: PMC8641806.

[337] Hoffman GJ, Liu H, Alexander NB, Tinetti M, Braun TM, Min LC. Posthospital Fall Injuries and 30-Day Readmissions in Adults 65 Years and Older. JAMA Netw Open. 2019 May 3;2(5):e194276. doi: 10.1001/jamanetworkopen.2019.4276. PMID: 31125100; PMCID: PMC6632136.

[338] Criss MG, Wingood M, Staples W, Southard V, Miller K, Norris TL, Avers D, Ciolek CH, Lewis CB, Strunk ER. APTA Geriatrics' Guiding Principles for Best Practices in Geriatric Physical Therapy: An Executive Summary. J Geriatr Phys Ther. 2022 April/June;45(2):70–75. doi: 10.1519/JPT.0000000000000342. PMID: 35384940.

[339] Cogan AM, Weaver JA, McHarg M, Leland NE, Davidson L, Mallinson T. Association of Length of Stay, Recovery Rate, and Therapy Time per Day With Functional Outcomes After Hip Fracture Surgery. JAMA Netw Open. 2020 Jan 3;3(1):e1919672. doi: 10.1001/jamanetworkopen.2019.19672. PMID: 31977059; PMCID: PMC6991278.

[340] National Quality Forum. (2022, December 29). *MAP PAC/LTC Workgroup: 2022–2023 Measures Under Consideration (MUC) Review Meeting.* Retrieved from *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97960.*

[341] *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report,* which is available on the SNF Quality Reporting Program Measures and Technical Information web page at *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

Facilities (SNFs) Technical Report [342] for measure specifications and additional details. We also refer readers to the SNF QRP section VII.C.1.b.(1) of this final rule for additional information on Measure Importance and Measure Testing.

(a) Interested Parties and TEP Input

We convened two TEP meetings (July 2021 and January 2022), as well as a Patient and Family Engagement Listening Session, to collect feedback from interested parties on the measure's potential use in quality programs in the future. The TEP members expressed support for the measure's validity and agreed with the conceptual and operational definition of the measure.

The feedback we received during the Patient and Family Engagement Listening Session demonstrated that this measure resonates with patients and caregivers. For example, participants' views of self-care and mobility were aligned with the functional domains captured by the measure, and participants found that those domains included critical aspects of care in post-acute care settings. Participants also emphasized the importance of measuring functional outcomes when assessing quality for SNF residents. We refer readers to the SNF QRP section VII.C.1.b.(3) of this final rule for additional discussion on the TEP.

(b) MAP Review

The DC Function measure was included as a SNF VBP measure under consideration in the publicly available ''2022 Measures Under Consideration List.'' [343] The MAP offered conditional support of the DC Function measure for rulemaking, contingent upon endorsement by the consensus-based entity, noting that the measure will add value to the Program because there are currently no measures related to functional status in the Program, and this measure serves as an indicator for whether the care provided is effective and high quality. We refer readers to section VII.C.1.b.(4) of this final rule for further details on the MAP's recommendations and the final 2022–2023 MAP recommendations available at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

We solicited public comment on our proposal to adopt the Discharge Function Score measure beginning with the FY 2027 SNF VBP program year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported adoption of the DC Function measure in the SNF VBP Program because it assesses performance on both self-care and mobility items. One commenter stated that implementing the measure in the FY 2027 program year allows SNFs enough time to evaluate their current performance on the measure.

Response: We thank the commenters for their feedback. We also note that many of the same commenters expressed support for the inclusion of this measure in both the SNF QRP and SNF VBP. We responded to those more general comments in section VII.C.1.b. of this final rule.

Comment: One commenter supported the proposal to adopt this measure for the SNF VBP Program, but they recommended that the measure be scored on the resident's change in the DC Function score so that the Program rewards facilities based on the degree of a resident's improvement in function rather than if they met or exceeded an expected discharge score.

Response: We appreciate the commenter's recommendation however, we believe the measure as proposed is the best measure for the Program at this time because it has strong reliability and validity, has received positive feedback from a TEP and other interested parties, and has high reportability and usability. We also do not believe at this time that rewarding facilities for any improvement in resident function, especially those residents who may not achieve a discharge function benchmark, are sufficient incentives for improving the quality of care for SNF residents. While we agree that it is important for facilities to track the amount of change that occurs over the course of a stay for its residents, we would like to point out that ''Change in Score'' measures are not as intuitive to interpret because the units of change and what constitutes a meaningful change has not been determined for residents with differing diagnoses and clinical complexities that seek care at SNFs. This is in contrast to the proposed Discharge Function Score measure which is presented as a simple proportion.

As stated in section VII.C.1.b.(3) of the proposed rule, a TEP was convened and asked whether they prefer a measure that is modeled after the currently adopted Discharge Mobility Score and Discharge Self Care Score measures, or one that is modeled after the currently adopted Change in Mobility Score and Change in Self Care Score measures. We note that the Discharge Mobility Score and Change in Mobility Score measures were highly correlated and did not appear to measure unique concepts. The Discharge Self Care Score and Change in Self Care Score measures were also highly correlated and did not appear to measure unique concepts. Because both the discharge and change measure types did not appear to measure unique concepts, the TEP favored the Discharge Mobility Score and Discharge Self Care Score measures over the Change in Mobility Score and Change in Self Care Score measures. Based on the TEP's recommendation to our contractor, we made a policy decision to pursue the DC Function measure for the measure of functional status in the SNF VBP Program.

Comment: A few commenters who supported the DC Function measure recommended that CMS include the expected discharge function score, a score that is already calculated during the measure evaluation, along with the observed function score on the provider reports, so that providers have transparency into their performance.

Response: We will take this feedback into consideration as we develop our quarterly confidential feedback reports that are provided after the end of the data submission period. We also note that many of the same commenters expressed this recommendation for both the SNF QRP and SNF VBP. We responded to those comments in section VII.C.1.b. of this final rule.

Comment: A few commenters did not support the adoption of the DC Function measure in the SNF VBP Program because the MDS-data are not validated for accuracy, and providers have not had enough time using the measure prior to use in a performance-based program.

Response: We thank the commenters for their feedback. As explained below, we are finalizing a proposal to validate the MDS data used to calculate SNF VBP measures, and we believe that this policy will help to ensure that those data are accurate for quality purposes. As stated in section VII.F.2 of this final rule, the SNF QRP is adopting this measure in FY 2025 SNF QRP year with data collection beginning with October 1, 2023 discharges. We are finalizing the adoption of this measure for the SNF VBP Program beginning with the FY 2027 program year, with data collection beginning with October 1, 2024

[342] *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report,* which is available on the SNF Quality Reporting Program Measures and Technical Information web page at *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

[343] 2022 Measures Under Consideration Spreadsheet available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

discharges. This timeline will enable SNFs to report the data for a full year in the SNF QRP before they are required to report them for the SNF VBP Program. We believe that reporting this measure in the SNF QRP for one year is sufficient time for providers to gain familiarity with the measure. As we stated in the proposed rule (88 FR 21372), the DC Function measure contains similar data elements to the Discharge Self-Care Score and Discharge Mobility Score measures, which have been included in the SNF QRP measure set for several years. We believe that SNFs are well acquainted with the Self-Care Score and Discharge Mobility Score measures so adopting the DC Function measure at a similar time for both the SNF QRP and SNF VBP Program is reasonable. We also note that many of the same commenters did not support the inclusion of this measure in both the SNF QRP and SNF VBP Program. We responded to those more general comments in section VII.C.1.b. of this final rule.

Comment: One commenter believed that SNFs will need to update their software in order to create and implement the measure's complex calculations, as well as to monitor the expected and observed discharge function score progression. This commenter also stated SNFs will need to provide additional training and education for clinical and administrative personnel with the adoption of new measures.

Response: We interpret the commenter to be saying that SNFs will need to update their software to perform the measure calculations prior to receiving the CMS generated reports, as well as provide training and education to their clinical staff on the DC Function measure and their administrative personnel on reporting the data or monitoring the data.

We acknowledge the commenter's concern regarding updating software; however, SNFs are not required to update their own software to successfully report the MDS items or monitor their performance on the DC Function measure. Additionally, we disagree that the adoption of the proposed measure would result in additional burden or require additional training. We did not propose to change the items SNFs report for the measure calculation nor the frequency at which SNFs would report these items. In fact, this measure uses the same set of MDS items that SNFs have been reporting at admission and discharge since October 1, 2018. We also will calculate this measure and provide SNFs with various educational resources on the DC Function measure they can use in preparation for reviewing and monitoring their own performance on this measure, thus eliminating the need for SNFs to create training and education for their clinical and administrative personnel.

After consideration of public comments, we are finalizing adoption of the Discharge Function Score measure for the SNF VBP Program beginning with the FY 2027 program year.

e. Adoption of the Number of Hospitalizations per 1,000 Long-Stay Resident Days Measure Beginning With the FY 2027 SNF VBP Program Year

(1) Background

Unplanned hospitalizations of long-stay residents can be disruptive and burdensome to residents. ''They can cause discomfort for residents, anxiety for loved ones, morbidity due to iatrogenic events, and excess healthcare costs.'' [344] Studies have found that many unplanned hospitalizations could have been safely avoided by early intervention by the facility. For example, one structured review by expert clinicians of hospitalizations of SNF residents found that two-thirds were potentially avoidable, citing a lack of primary care clinicians on-site and delays in assessments and lab orders as primary reasons behind unplanned hospitalizations.[345] Another study found that standardizing advanced care planning and physician availability has a considerable impact on reducing hospitalizations.[346] The Missouri Quality Initiative reduced hospitalizations by 30 percent by having a clinical resource embedded to influence resident care outcomes. Another study found that reducing hospitalizations did not increase the mortality risk for long-stay nursing home residents.[347]

A review of data that were publicly reported on Care Compare shows that there is considerable variation in performance across nursing homes when it comes to unplanned hospitalizations, suggesting that improvement is possible through modification of facility-led processes and interventions. Specifically, performance on this measure ranges from 0.841 hospital admissions per 1,000 long-stay resident days at the 10th percentile to 2.656 hospital admissions per 1,000 long-stay resident days at the 90th percentile.[348] In other words, the top decile of performers (10th percentile) has less than half the number of hospitalizations compared to the bottom decile (90th percentile). We also reported in 2020 that the rate of unplanned hospitalizations was 1.4 per 1,000 nursing home resident days, suggesting these disruptive events are fairly common.[349] Adopting this measure will align measures between Care Compare and the SNF VBP program without increasing the reporting burden.

Although the Long Stay Hospitalization measure is not specified under section 1899B(c)(1) of the Act, it aligns with the topics listed under section 1888(h)(2)(A)(ii) of the Act. We believe this outcome measure supports the Program's goals to improve the quality of care provided to Medicare beneficiaries throughout their entire SNF stay. Furthermore, the measure will align the Program with the Care Coordination domain of CMS' Meaningful Measures 2.0 Framework.

We examined the relationship between long-stay hospitalization rates and other measures of quality from CMS' Five-Star Quality Rating System using data from the December 2019 Nursing Home Compare update. Analyses showed that facilities with lower hospitalization rates tend to perform better on other dimensions of quality such as health inspection survey results, staffing level, other quality measures, and overall ratings.

Although the Long Stay Hospitalization measure is a long-stay measure, we believe that including a long-stay measure in the SNF VBP Program is appropriate because it will better capture the quality of care provided to the entirety of the population that resides in facilities that

[344] Ouslander, J.G., Lamb, G., Perloe, M., Givens, J.H., Kluge, L., Rutland, T., Atherly, A., & Saliba, D. (2010). Potentially avoidable hospitalizations of nursing home residents: frequency, causes, and costs. Journal of the American Geriatrics Society, 58(4), 627–635. *https://doi.org/10.1111/j.1532-5415.2010.02768.x.*

[345] Ouslander, J.G., Lamb, G., Perloe, M., Givens, J.H., Kluge, L., Rutland, T., Atherly, A., & Saliba, D. (2010). Potentially avoidable hospitalizations of nursing home residents: frequency, causes, and costs. Journal of the American Geriatrics Society, 58(4), 627–635. *https://doi.org/10.1111/j.1532-5415.2010.02768.x.*

[346] Giger, M., Voneschen, N., Brunkert, T., & Zúniga, F. (2020). Care workers' view on factors leading to unplanned hospitalizations of nursing home residents: a cross-sectional multicenter study. Geriatric Nursing, 41(2), 110–117.

[347] Feng, Z., Ingber, M.J., Segelman, M., Zheng, N.T., Wang, J.M., Vadnais, A., . . . & Khatutsky, G. (2018). Nursing facilities can reduce avoidable hospitalizations without increasing mortality risk for residents. Health Affairs, 37(10), 1640–1646.

[348] Data is pulled from the public facing scorecard in 2020, available at *https://www.medicaid.gov/state-overviews/scorecard/hospitalizations-per-1000-long-stay-nursing-home-days/index.html.*

[349] Data is pulled from the public facing scorecard in 2020, available at *https://www.medicaid.gov/state-overviews/scorecard/hospitalizations-per-1000-long-stay-nursing-home-days/index.html.*

are dually certified as SNFs and nursing facilities, including long-stay residents who continue to receive Medicare coverage for certain services provided by nursing facilities. We discussed the potential of including long-stay measures in the SNF VBP Program in the FY 2022 SNF PPS final rule Summary of Comments Received on Potential Future Measures for the SNF VBP Program (86 FR 42507 through 42510). Specifically, we stated that the majority of long-stay residents are Medicare beneficiaries, regardless of whether they are in a Medicare Part A SNF stay, because they are enrolled in Medicare Part B and receive Medicare coverage of certain services provided by long-term care facilities even if they are a long-stay resident. We did not receive any negative comments on inclusion of this specific Long Stay Hospitalization measure or long-stay measures generally in the Program in response to the request for comment.

(2) Overview of Measure

The Long Stay Hospitalization measure calculates the number of unplanned inpatient admissions to an acute care hospital or critical access hospital, or outpatient observation stays that occurred among long-stay residents per 1,000 long-stay resident days using 1 year of Medicare fee-for-service (FFS) claims data. A long-stay day is defined as any day after a resident's one-hundredth cumulative day in the nursing home or the beginning of the 12-month target period (whichever is later) and until the day of discharge, the day of death, or the end of the 12-month target period (whichever is earlier). We proposed to risk adjust this measure, as explained in more detail below.

(a) Measure Applications Partnership (MAP) Review

We included the Long Stay Hospitalization measure in the publicly available ''2022 Measures Under Consideration List.'' [350] The MAP offered conditional support of the Long Stay Hospitalization measure for rulemaking, contingent upon endorsement by the consensus-based entity, noting that the measure will add value to the Program because unplanned hospitalizations are disruptive and burdensome to long-stay residents. We refer readers to the final 2022–2023 MAP recommendations available at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

(3) Data Sources

The Long Stay Hospitalization measure is calculated using Medicare FFS claims data. We use the inpatient hospital claims data to determine the hospital admission, outpatient hospital claims data to determine the outpatient observation stay, and items from the Minimum Data Set for building resident stays and for risk-adjustment.

(4) Inclusion and Exclusion Criteria

All Medicare beneficiaries enrolled in both Part A and Part B are included. The measure excludes any resident enrolled in Medicare managed care during any portion of the resident's stay. The measure also excludes all days and any hospital admissions during which the resident was enrolled in hospice.

The measure does not count days prior to a resident's 101st cumulative day, which is when the resident meets long-stay criteria. Furthermore, we do not include any long-stay days prior to the beginning of the applicable performance period. For example, if a resident becomes a long-stay resident on September 25, 2024, and is discharged on October 5, 2024, we would only count 5 days in the denominator during the performance period for the FY 2027 program year.

Any days a resident was not in the facility for any reason will not be counted in the denominator, defined as the total observed number of long stay days at the facility. This means we do not count in the denominator any days the resident is admitted to another type of inpatient facility, or days temporarily residing in the community, so long as the NF with beds that are also certified as SNF beds submits an MDS discharge assessment for the temporary discharge. For example, if a resident became a long-stay resident on December 20, but stayed with family on December 24 and December 25 but returned to the facility on December 26, we would not count those two days (24 and 25) in the denominator because the NF with beds that are also certified as SNF beds completed an MDS discharge assessment. We would also not count the days when a resident was admitted to a hospital, and therefore, is not residing at the facility in the denominator.

We will not count an observed hospitalization of a resident, the numerator count, if the hospitalization occurred while the resident was not in the facility and had a completed MDS discharge assessment for the temporary discharge. In the example in the prior paragraph, if the resident was admitted to the hospital on December 25, during which they were residing with family with a completed MDS temporary discharge assessment, the admission would not be counted as a hospitalization for the NF with beds that are also certified as SNF beds (in the numerator). If, however, the resident returned to the NF with beds that are also certified as SNF beds on December 26 and was admitted to the hospital on December 27, then it would count as a hospitalization (in the numerator).

If a resident spends 31 or more days in a row residing outside the NF with beds that are also certified as SNF beds, which could be in another facility or in the community, we will consider the resident discharged and they will no longer meet long-stay status. If a resident is discharged and then admitted to the same facility within 30 days, we will consider the resident still in a long-stay status, and we will count the days in this admission in the measure denominator.

The measure numerator includes all admissions to an acute care hospital or critical access hospital, for an inpatient or outpatient observation stay, that occur while the resident meets the long-stay status criteria. Observation stays are included in the numerator regardless of diagnosis. Planned inpatient admissions are not counted in the numerator since they are unrelated to the quality of care at the facility. Hospitalizations are classified as planned or unplanned using the same version of CMS' Planned Readmissions Algorithm that is used to calculate the percentage of short-stay residents who were re-hospitalized after a nursing home admission in the Nursing Home Compare Five-Star Rating System. The algorithm identifies planned admission using the principal discharge diagnosis category and all procedure codes listed on inpatient claims, coded using the AHRQ Clinical Classification System (CCS) software.

(5) Risk Adjustment

The risk adjustment model used for this measure is a negative binomial regression. Specifically, we proposed to risk adjust the observed number of hospitalizations after the resident met the long-stay status to determine the expected number of hospitalizations for each long-stay resident given the resident's clinical and demographic profile. The goal of risk adjustment is to account for differences across facilities in medical acuity, functional impairment, and frailty of the long-stay residents but not factors related to the quality of care provided by the facility. The data for the risk adjustment model

[350] 2022 Measures Under Consideration Spreadsheet available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

are derived from Medicare inpatient claims data prior to the day the resident became a long-stay resident and from the most recent quarterly or comprehensive MDS assessment within 120 days prior to the day the resident became a long-stay resident.

The risk adjustment variables derived from the claims-based data include age, sex, number of hospitalizations in the 365 days before the day the resident became a long-stay resident or beginning of the 1-year measurement period (whichever is later), and an outcome-specific comorbidity index. The MDS-based covariates span multiple domains including functional status, clinical conditions, clinical treatments, and clinical diagnoses.

We refer readers to the measure specifications for additional details on the risk-adjustment model for this measure available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/Nursing-Home-Compare-Claims-based-Measures-Technical-Specifications-April-2019.pdf.*

(6) Measure Calculation

To get the risk adjusted rate (risk standardized rate), we take the observed Long Stay Hospitalization rate divided by the expected Long Stay Hospitalization rate, multiplied by the national Long Stay Hospitalization rate, as shown by the following formula:

$$Risk\ Standardized\ Rate = \left(\frac{Observed\ Rate}{Expected\ Rate}\right) \times National\ Rate$$

The observed Long Stay Hospitalization rate is the actual number of hospital admissions or observation stays that met the previously discussed inclusion criteria divided by the actual total number of long-stay days that met the previously discussed inclusion criteria divided by 1,000 days. The observed rate is shown by the following formula:

$$Observed\ Rate = \frac{Observed\ Number\ of\ Hospitalizations}{Observed\ Number\ of\ Long\ Stay\ \ Days/1{,}000}$$

The expected Long Stay Hospitalization rate is the expected number of hospital admission or observation stays that were calculated using the risk adjustment methodology discussed in section VIII.B.4.e.(5) of this final rule, divided by the actual total number of long-stay days that met the previously discussed inclusion criteria divided by 1,000 days. The expected Long Stay Hospitalization rate is shown by the following formula:

$$Expected\ Rate = \frac{Predicted\ Number\ of\ Hospitalizations}{Observed\ Number\ of\ Long\ Stay\ Days\ at\ Facility/1{,}000}$$

The national Long Stay Hospitalization rate is the total number of inpatient hospital admission or observation stays meeting the numerator criteria, divided by the total number of all long stay days that met the denominator criteria divided by 1,000. The national Long Stay Hospitalization rate is shown by the following formula:

$$National\ Rate = \frac{Number\ of\ Long\ Stay\ Hospitalizations}{Number\ of Long\ Stay\ Days/1{,}000}$$

We refer readers to the measure specifications for additional details for this measure calculation available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/Nursing-Home-Compare-Claims-based-Measures-Technical-Specifications-April-2019.pdf.*

We solicited public comment on our proposal to adopt the Number of Hospitalizations per 1,000 Long-Stay Resident Days measure beginning with the FY 2027 SNF VBP program year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the proposal to adopt the measure. One commenter suggested that CMS monitor rates of hospitalization for long-stay residents to assess whether this measure will remain appropriate in the long-term.

Response: We thank the commenters for their support. We agree with the suggestion and intend to monitor all SNF VBP Program measures to ensure that they remain relevant to the care quality provided to Medicare beneficiaries in this setting.

Comment: Some commenters supported the measure's adoption but expressed concerns about its use in the Program. One commenter wondered what this measure adds to the Program that isn't captured by the proposed SNF WS PPR measure. Another commenter stated its belief that CMS should focus the SNF VBP Program on Medicare Part A patients, which does not include long-stay residents, because the Program itself affects payments for Part A services. Two commenters were concerned that the measure excludes Medicare Advantage residents, thus not covering a significant portion of Medicare beneficiaries.

Response: We thank the commenters for their feedback. As we stated in the proposed rule (88 FR 21373 through 21374), our analysis of the relationship between long-stay hospitalization rates and other measures of quality from

CMS's Five-Star Quality Rating System showed that facilities with lower hospitalization rates tend to perform better on other dimensions of quality such as health inspection survey results, staffing level, other quality measures, and overall ratings. We further explained our reasoning for including a long-stay measure in the SNF VBP Program in the proposed rule (88 FR 21370), where we stated that we believe long-stay measures better capture the quality of care provided to the entirety of the population that resides in facilities that are dually certified as SNFs and nursing facilities. Long-stay residents who are enrolled in Medicare Part B receive Medicare Part B coverage for certain services provided by nursing facilities. We believe that presenting more quality information for beneficiaries helps improve the care they receive and the health system generally. We would also like to clarify that the SNF WS PPR assesses readmission rates for SNF residents who are admitted to a short-stay acute care hospital or long-term care hospital with a principal diagnosis considered to be unplanned and potentially preventable while within SNF care, while the Long-Stay Hospitalization measure focuses on the risks experienced by long-stay residents. We therefore view these measures as complementary assessments of readmissions in dually certified facilities. The majority of long-stay residents are enrolled in Medicare Part B. For those residents, Medicare Part B provides coverage of certain services, such as physical therapy, that are provided by the nursing facility. We therefore believe that the measure is appropriate for the Program.

We also appreciate commenters' concerns about Medicare Advantage residents. However, we would like to clarify that our Star Ratings system provides quality information to Medicare beneficiaries about the care they receive from the specific facility regardless of whether the beneficiary is enrolled in the Medicare FFS program or in a Medicare Advantage plan. We are also interested in including Medicare Advantage beneficiaries in the measure's calculations, but Medicare Advantage claims are not generally available for our use on the same timing or in the same way that FFS claims are used to calculate this measure.

Comment: Some commenters opposed the proposal to adopt this measure. One commenter did not believe the measure aligned with the Program's intent to link Medicare FFS reimbursement with care and outcomes experienced by Medicare FFS beneficiaries. A few commenters were concerned about assessing facilities using long-stay measures for a short-stay Medicare benefit. One commenter worried that the measure would impose additional burdens on SNFs.

Response: We thank the commenters for this feedback. However, as we explained in the proposed rule (88 FR 21373 through 21374), performance on the Long Stay Hospitalization measure is correlated with numerous other measures of quality in the SNF sector, meaning that, in our view, the measure supports quality improvement in the SNF sector. We continue to believe that measures like this one provide significant benefits to Medicare beneficiaries.

We would also like to clarify that the Long Stay Hospitalization measure is calculated using Medicare claims data, so it imposes no additional reporting or validation burden on SNFs.

After consideration of public comments, we are finalizing adoption of the Number of Hospitalizations per 1,000 Long-Stay Resident Days measure beginning with the FY 2027 SNF VBP program year.

f. Scoring of SNF Performance on the Nursing Staff Turnover, Falls With Major Injury (Long-Stay), and Long Stay Hospitalization Measures

(1) Background

In the FY 2017 SNF PPS final rule (81 FR 52000 through 52001), we finalized a policy to invert SNFRM measure rates such that a higher measure rate reflects better performance on the SNFRM. In that final rule, we also stated our belief that this inversion is important for incentivizing improvement in a clear and understandable manner because a ''lower is better'' rate could cause confusion among SNFs and the public. In the FY 2023 SNF PPS final rule (87 FR 47568), we applied this policy to the SNF HAI measure such that a higher measure rate reflects better performance on the SNF HAI measure. We also stated our intent to apply this inversion scoring policy to all measures in the Program for which the calculation produces a ''lower is better'' measure rate. We continue to believe that inverting measure rates such that a higher measure rate reflects better performance on a measure is important for incentivizing improvement in a clear and understandable manner.

This measure rate inversion scoring policy does not change the measure specifications or the calculation method. We use this measure rate inversion as part of the scoring methodology under the SNF VBP Program. The measure rate inversion is part of the methodology we use to generate measure scores, and resulting SNF Performance Scores, that are clear and understandable for SNFs and the public.

(2) Inversion of the Nursing Staff Turnover, Falls With Major Injury (Long-Stay), and Long Stay Hospitalization Measures Rates for SNF VBP Program Scoring Purposes

In sections VII.B.4.b., VII.B.4.c., and VII.B.4.e. of the proposed rule, we stated that a lower measure rate for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and Long Stay Hospitalization measures indicate better performance on those measures. Therefore, we proposed to apply our measure rate inversion scoring policy to these measures. We proposed to calculate the score for these measures for the SNF VBP Program by inverting the measure rates using the calculations shown in Table 16. We did not propose to apply this policy to the DC Function measure because that measure, as currently specified and calculated, produces a ''higher is better'' measure rate.

TABLE 16: Proposed Measure Inversion Calculation Formulas

Measure	Inversion Calculation Formula
Nursing Staff Turnover measure	*Nursing Staff Turnover Inverted Rate = 1 – Nursing Staff Turnover Rate*
Falls with Major Injury (Long-Stay) measure	$\textit{Falls with Major Injury (Long Stay) Inverted Rate} = 1 - \left(\frac{\textit{Facility's Falls with Major Injury (Long Stay) Rate}}{100}\right)$
Long Stay Hospitalization measure	$\textit{Long Stay Hospitalization Inverted Rate} = 1 - \left(\frac{\textit{Long Stay Hospitalization Risk Standardize Rate}}{1{,}000}\right)$

We believe that inverting the measure rates for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and Long Stay Hospitalization measure is important for incentivizing improvement in a clear and understandable manner, and for ensuring a consistent message that a higher measure rate reflects better performance on the measures.

We solicited public comment on our proposal to invert the measure rates for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and Long Stay Hospitalization measures for the purposes of scoring under the SNF VBP Program.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal to invert the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and Long Stay Hospitalization measure rates for SNF VBP program scoring purposes because the proposal is important for incentivizing improvement in a clear and understandable manner, and for ensuring a consistent message that a higher measure rate reflects better performance.

Response: We thank this commenter for their support. We agree that this proposed score inversion will provide a clearer depiction of quality in our performance scoring.

Comment: One commenter recommended that in addition to the proposed inversion of the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and Long Stay Hospitalization measure rates for SNF VBP Program scoring purposes, non-inverted rates be included in feedback reports to providers to help them track their performance relative to benchmark rates in their quality improvement effort.

Response: We thank this commenter for their recommendation. We note that we currently include the non-inverted rates for the SNFRM in the quarterly confidential feedback reports, and we intend to continue that practice for all new measures for which we invert the measure rates for scoring purposes. As mentioned in the proposed rule (88 FR 21376), the measure rate inversion is solely part of the methodology we use to generate measure scores and resulting SNF Performance Scores.

Comment: One commenter opposed the proposal to invert the nursing staff turnover, falls with major injury (long-stay), and long stay hospitalization measure rates for SNF VBP program scoring purposes. This commenter believes the proposed score inversion overly complicates an already complex quality initiative. The commenter further expressed that the application of inverted scores is inconsistent with public reporting for other measures.

Response: We believe that our policy to invert measure rates such that a higher measure rate reflects better performance is important for incentivizing improvement through clear and understandable SNF Performance Scores. This measure rate inversion scoring policy is only used for the purposes of generating SNF Performance Scores under the SNF VBP Program's scoring methodology. The measure rate inversions do not change the measure specifications and are not publicly reported.

After consideration of public comments, we are finalizing our proposal to invert the measure rates for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and Long Stay Hospitalization measures for the purposes of scoring under the SNF VBP Program.

g. Confidential Feedback Reports and Public Reporting for Quality Measures

Our confidential feedback reports and public reporting policies are codified at § 413.338(f) of our regulations. In the FY 2023 SNF PPS final rule (87 FR 47591 through 47592), we revised our regulations such that the confidential feedback reports and public reporting policies apply to each measure specified for a fiscal year, which includes the Nursing Staff Turnover measure beginning with the FY 2026 program year, and the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures beginning with the FY 2027 program year.

We did not propose any changes to these policies in the proposed rule.

C. SNF VBP Performance Periods and Baseline Periods

1. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods and baseline periods under the SNF VBP Program. In the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), we adopted a policy whereby we will automatically adopt the performance period and baseline period for a SNF VBP program year by advancing the performance period and baseline period by 1 year from the previous program year. In the FY 2023 SNF PPS final rule (87 FR 47580 through 47583), we adopted performance periods and baseline periods for three new quality measures beginning with the FY 2026 program year: (1) SNF HAI measure, (2) Total Nurse Staffing measure, and (3) DTC PAC SNF measure, and finalized the application of our policy to automatically adopt performance periods and baseline periods for subsequent program years to those new measures.

2. SNFRM Performance and Baseline Periods for the FY 2024 SNF VBP Program Year

Under the policy finalized in the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), the baseline period for the SNFRM for the FY 2024 program year would be FY 2020 and the performance period for the SNFRM for the FY 2024 program year would be FY

2022. However, in the FY 2022 SNF PPS final rule (85 FR 42512 through 42513), we updated the FY 2024 baseline period for the SNFRM to FY 2019 since the ECE we granted on March 22, 2020, due to the PHE for COVID–19, excepted qualifying claims for a 6-month period in FY 2020 (January 1, 2020 through June 30, 2020) from the calculation of the SNFRM.[351] [352] We refer readers to that final rule for additional discussion of our considerations for updating the FY 2024 baseline period for the SNFRM. Therefore, for the FY 2024 program year, the baseline period for the SNFRM is FY 2019 and the performance period for the SNFRM is FY 2022.

3. Performance Periods and Baseline Periods for the Nursing Staff Turnover, Falls With Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization Measures

a. Performance Periods for the Nursing Staff Turnover, Falls With Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization Measures

In considering the appropriate performance periods for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures, we recognize that we must balance the length of the performance periods with our need to calculate valid and reliable performance scores and announce the resulting payment adjustments no later than 60 days prior to the program year involved, in accordance with section 1888(h)(7) of the Act. In addition, we refer readers to the FY 2017 SNF PPS final rule (81 FR 51998 through 51999) for a discussion of the factors we should consider when specifying performance periods for the SNF VBP Program, as well as our stated preference for 1-year performance periods. Based on these considerations, we believe that 1-year performance periods for these measures would be operationally feasible for the SNF VBP Program and would provide sufficiently accurate and reliable measure rates and resulting performance scores for the measures.

We also recognize that we must balance our desire to specify performance periods for a fiscal year as close to the fiscal year's start date as possible to ensure clear connections between quality measurement and value-based payment with our need to announce the net results of the Program's adjustments to Medicare payments not later than 60 days prior to the fiscal year involved, in accordance with section 1888(h)(7) of the Act. In considering these constraints, and in alignment with other SNF VBP measures, we believe that performance periods that occur 2 fiscal years prior to the applicable fiscal program year is most appropriate for these measures.

For these reasons, we proposed to adopt the following performance periods:

- FY 2024 (October 1, 2023 through September 30, 2024) as the performance period for the Nursing Staff Turnover measure for the FY 2026 SNF VBP program year.
- FY 2025 (October 1, 2024, through September 30, 2025) as the performance period for the Falls with Major Injury (Long-Stay) measure for the FY 2027 SNF VBP program year.
- FY 2025 (October 1, 2024 through September 30, 2025) as the performance period for the DC Function measure for the FY 2027 SNF VBP program year.
- FY 2025 (October 1, 2024 through September 30, 2025) as the performance period for the Long Stay Hospitalization measure for the FY 2027 SNF VBP program year.

In alignment with the previously adopted SNF VBP measures, we also proposed that, for these measures, we will automatically adopt the performance period for a SNF VBP program year by advancing the beginning of the performance period by 1 year from the previous program year.

We solicited public comment on our proposals to adopt performance periods for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures. We provide a summary of the comments we received and our responses in the next section. As stated in that section, we are finalizing the performance periods for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures.

b. Baseline Periods for the Nursing Staff Turnover, Falls With Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization Measures

In the FY 2016 SNF PPS final rule (80 FR 46422) we discussed that, as with other Medicare quality programs, we generally adopt baseline periods for a fiscal year that occurs prior to the performance periods for that fiscal year to establish measure performance standards. We also discussed our intent to adopt baseline periods that are as close as possible in duration as performance periods for a fiscal year, as well as our intent to seasonally align baseline periods with performance periods to avoid any effects on quality measurement that may result from tracking SNF performance during different times in a year. Therefore, to align with the performance period length for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures, we proposed to adopt 1-year baseline periods for those measures.

We also recognize that we are required, under section 1888(h)(3)(C) of the Act, to calculate and announce performance standards no later than 60 days prior to the start of performance periods. Therefore, we believe that baseline periods that occur 4 fiscal years prior to the applicable fiscal program year, and 2 fiscal years prior to the performance periods, is most appropriate for these measures and will provide sufficient time to calculate and announce performance standards prior to the start of the performance periods.

For these reasons, we proposed to adopt the following baseline periods:

- FY 2022 (October 1, 2021 through September 30, 2022) as the baseline period for the Nursing Staff Turnover measure for the FY 2026 SNF VBP program year.
- FY 2023 (October 1, 2022 through September 30, 2023) as the baseline period for the Falls with Major Injury (Long-Stay) measure for the FY 2027 SNF VBP program year.
- FY 2023 (October 1, 2022 through September 30, 2023) as the baseline period for the DC Function measure for the FY 2027 SNF VBP program year.
- FY 2023 (October 1, 2022 through September 30, 2023) as the baseline period for the Long Stay Hospitalization measure for the FY 2027 SNF VBP program year.

In alignment with the previously adopted SNF VBP measures, we also proposed that, for these measures, we will automatically adopt the baseline period for a SNF VBP program year by advancing the beginning of the baseline period by 1 year from the previous program year.

We solicited public comment on our proposals to adopt baseline periods for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

[351] CMS. (2020). Press Release: CMS Announces Relief for Clinicians, Providers, Hospitals, and Facilities Participating in Quality Reporting Programs in Response to COVID–19. *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[352] CMS memorandum (2020) available at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

Comment: One commenter supported the performance periods and baseline periods for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures as proposed.

Response: We thank the commenter for their support of the performance periods and baseline periods for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures.

After consideration of public comments, we are finalizing the performance periods and baseline periods for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures.

4. Performance Periods and Baseline Periods for the SNF WS PPR Measure Beginning With the FY 2028 SNF VBP Program Year

a. Performance Periods for the SNF WS PPR Measure Beginning With the FY 2028 SNF VBP Program Year

The SNF WS PPR measure is calculated using 2 consecutive years of Medicare FFS claims data, and therefore, we proposed to adopt a 2-year performance period for this measure. During the re-specification process for the SNF WS PPR measure, we determined that using 2 years of data improved the measure reliability. Specifically, the intraclass correlation coefficient (with the Spearman-Brown correction applied) for the SNF WS PPR measure was 0.71 compared to 0.56 for the SNFRM. We refer readers to section VIII.B.2. of this final rule and the SNF WS PPR measure technical specifications, available at *https://www.cms.gov/files/document/snfvbp-snfwsppr-draft-technical-measure-specification.pdf,* for additional details.

Accordingly, we proposed to adopt October 1, 2024 through September 30, 2026 (FY 2025 and FY 2026) as the performance period for the SNF WS PPR measure for the FY 2028 SNF VBP program year. We believe that using October 1, 2024 through September 30, 2026 (FY 2025 and FY 2026) as the performance period for the FY 2028 program year best balances our need for sufficient data to calculate valid and reliable performance scores with our requirement under section 1888(h)(7) of the Act to announce the resulting payment adjustments no later than 60 days prior to the program year involved.

In alignment with the previously adopted SNF VBP measures, we also proposed that for the SNF WS PPR measure, we will automatically adopt the performance period for a SNF VBP program year by advancing the beginning of the performance period by 1 year from the previous program year.

We solicited public comment on our proposals related to the performance periods for the SNF WS PPR measure beginning with the FY 2028 program year. We provide a summary of the comments we received and our responses in the next section. As stated in that section, we are finalizing the performance periods for the SNF WS PPR measure beginning with the FY 2028 program year.

b. Baseline Periods for the SNF WS PPR Measure Beginning With the FY 2028 SNF VBP Program Year

Our policy is to generally adopt a baseline period for a fiscal year that occurs prior to the performance period for that fiscal year in order to establish a measure's performance standards. We also generally adopt baseline periods that are as close as possible in duration as the performance period for a fiscal year, as well as seasonally aligning the baseline periods with performance periods to avoid any effects on quality measurement that may result from tracking SNF performance during different times in a year. Therefore, to align with the performance period length for the SNF WS PPR measure, we proposed a 2-year baseline period for this measure.

We also recognize that we are required, under section 1888(h)(3)(C) of the Act, to calculate and announce performance standards no later than 60 days prior to the start of the performance period. Therefore, we believe that a baseline period that begins 6 fiscal years prior to the applicable fiscal program year, and 3 fiscal years prior to the applicable performance period, is most appropriate for the SNF WS PPR measure and will provide sufficient time to calculate and announce performance standards prior to the start of the performance period. For these reasons, we proposed to adopt October 1, 2021 through September 30, 2023 (FY 2022 and FY 2023) as the baseline period for the SNF WS PPR measure for the FY 2028 SNF VBP program year.

In alignment with the previously adopted SNF VBP measures, we also proposed that for the SNF WS PPR measure, we will automatically adopt the baseline period for a SNF VBP program year by advancing the beginning of the baseline period by 1 year from the previous program year.

We solicited public comment on our proposals related to the baseline periods for the SNF WS PPR measure beginning with FY 2028 program year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed performance periods and baseline periods for the SNF WS PPR measure.

Response: We thank the commenter for their support of the performance periods and baseline periods for the SNF WS PPR measure beginning with the FY 2028 program year.

After consideration of public comments, we are finalizing the performance periods and baseline periods for the SNF WS PPR measure beginning with the FY 2028 program year.

c. SNFRM and SNF WS PPR Performance Period and Baseline Period Considerations

As discussed in the previous section, we are finalizing our proposal that the first performance period for the SNF WS PPR measure will be October 1, 2024 through September 30, 2026 (FY 2025 and FY 2026), and the first baseline period will be October 1, 2021 through September 30, 2023 (FY 2022 and FY 2023). In section VIII.B.3. of this final rule, we are finalizing our proposal to replace the SNFRM with the SNF WS PPR beginning with the FY 2028 program year. Therefore, the last program year that will include the SNFRM will be FY 2027. The last performance period for the SNFRM will be FY 2025 and the last baseline period will be FY 2023. We note that because the SNF WS PPR measure is a 2-year measure and the SNFRM is a 1-year measure, the data used to calculate the baseline and performance period for the SNF WS PPR measure for the FY 2028 program year will include data that is also used to calculate the baseline and performance period for the SNFRM for the FY 2027 program year. We believe the overlap is necessary to ensure that we can transition from the SNFRM to the SNF WS PPR seamlessly, without any gaps in the use of either measure.

D. SNF VBP Performance Standards

1. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy. In the FY 2019 SNF PPS final rule (83 FR 39276 through 39277), we also adopted a policy allowing us to

correct the numerical values of the performance standards. Further, in the FY 2023 SNF PPS final rule (87 FR 47583 through 47584), we amended the definition of ''Performance Standards,'' redesignated that definition as § 413.338(a)(12) and added additional detail for our performance standards correction policy at § 413.338(d)(6).

We adopted the final numerical values for the FY 2024 performance standards in the FY 2022 SNF PPS final rule (86 FR 42513) and adopted the final numerical values for the FY 2025 performance standards in the FY 2023 SNF PPS final rule (87 FR 47584).

We did not propose any changes to these performance standards policies.

2. Performance Standards for the FY 2026 Program Year

In the FY 2023 SNF PPS final rule (87 FR 47564 through 47576), we adopted two new quality measures for the FY 2026 program year: SNF HAI and Total Nurse Staffing measures. In section VIII.B.4.b. of this final rule, we are also finalizing adoption of the Nursing Staff Turnover measure beginning with the FY 2026 program year. We are finalizing that the performance period for the Nursing Staff Turnover measure for the FY 2026 program year will be FY 2024 (October 1, 2023 through September 30, 2024). Therefore, the FY 2026 program year will consist of four measures (SNFRM, SNF HAI, Total Nurse Staffing, and Nursing Staff Turnover measures).

To meet the requirements at section 1888(h)(3)(C) of the Act, we are providing the final numerical performance standards for the FY 2026 program year for the three previously adopted measures (SNFRM, SNF HAI, and Total Nurse Staffing measures), as well as the Nursing Staff Turnover measure. In accordance with our previously finalized methodology for calculating performance standards (81 FR 51996 through 51998), the final numerical values for the FY 2026 program year performance standards are shown in Table 17.

TABLE 17—FINAL FY 2026 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure short name	Achievement threshold	Benchmark
SNFRM	0.78800	0.82971
SNF HAI Measure	0.92315	0.95004
Total Nurse Staffing Measure	3.18523	5.70680
Nursing Staff Turnover Measure	0.35912	0.72343

3. Performance Standards for the DTC PAC SNF Measure for the FY 2027 Program Year

In the FY 2023 SNF PPS final rule (87 FR 47576 through 47580), we adopted the DTC PAC SNF measure beginning with the FY 2027 program year. In that final rule (87 FR 47582 through 47583), we also finalized that the baseline and performance periods for the DTC PAC SNF measures would be 2 consecutive years, and that FY 2024 and FY 2025 would be the performance period for the DTC PAC SNF measure for the FY 2027 program year.

To meet the requirements at section 1888(h)(3)(c) of Act, we are providing the final numerical performance standards for the DTC PAC SNF measure for the FY 2027 program year. In accordance with our previously finalized methodology for calculating performance standards (81 FR 51996 through 51998), the final numerical values for the DTC PAC SNF measure for the FY 2027 program year performance standards are shown in Table 18.

We note that we will provide the estimated numerical performance standard values for the remaining measures applicable in the FY 2027 program year in the FY 2025 SNF PPS proposed rule.

TABLE 18—FINAL FY 2027 SNF VBP PROGRAM PERFORMANCE STANDARDS FOR THE DTC PAC SNF MEASURE

Measure short name	Achievement threshold	Benchmark
DTC PAC SNF Measure	0.42946	0.66370

E. SNF VBP Performance Scoring Methodology

1. Background

Our performance scoring policies are codified at § 413.338(d) and (e) of our regulations. We also refer readers to the following prior final rules for detailed background on the scoring methodology for the SNF VBP Program:

- In the FY 2017 SNF PPS final rule (81 FR 52000 through 52005), we finalized several scoring methodology policies, including a policy to use the higher of a SNF's achievement and improvement scores as that SNF's performance score for a given program year.
- In the FY 2018 SNF PPS final rule (82 FR 36614 through 36616), we finalized: (1) a rounding policy, (2) a logistic exchange function, (3) a 60 percent payback percentage, and (4) a SNF performance ranking policy.
- In the FY 2019 SNF PPS final rule (83 FR 39278 through 39281), we finalized several scoring methodology policies, including a scoring policy for SNFs without sufficient baseline period data and an extraordinary circumstances exception policy.
- In the FY 2022 SNF PPS final rule (86 FR 42513 through 42515), we finalized a special scoring and payment policy for the FY 2022 SNF VBP Program due to the impact of the PHE for COVID–19.
- In the FY 2023 SNF PPS final rule (87 FR 47584 through 47590), we finalized a special scoring and payment policy for the FY 2023 SNF VBP Program due to the continued impact of the PHE for COVID–19. In that final rule, we also finalized several scoring methodology policies to accommodate the addition of new measures to the Program, including: (1) case minimum and measure minimum policies, including case minimums for the SNFRM, SNF HAI, Total Nurse Staffing, and DTC PAC SNF measures, (2) updates to the scoring policy for SNFs without sufficient baseline period data, (3) removal of the low-volume adjustment policy, and (4) a measure-level and normalization scoring policy to replace the previously adopted scoring methodology policies beginning with the FY 2026 program year.

2. Case Minimum and Measure Minimum Policies

a. Background

We refer readers to the FY 2023 SNF PPS final rule (87 FR 47585 through 47587) for a detailed description of our considerations for adopting case minimums and measure minimums. Our case minimum and measure minimum policies are also codified at § 413.338(b) of our regulations.

We proposed to adopt the Nursing Staff Turnover measure beginning with the FY 2026 program year; the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures beginning with the FY 2027 program year; and the SNF WS PPR measure beginning with the FY 2028 program year. Therefore, we also proposed to adopt case minimums for the new measures and proposed to update the previously finalized measure minimum for the FY 2027 program year. Although the addition of the Nursing Staff Turnover measure beginning with FY 2026 will increase the total number of measures for that program year, we believe that the previously finalized measure minimum of two measures remains sufficient for that program year.

b. Case Minimums During a Performance Period for the Nursing Staff Turnover, Falls With Major Injury (Long-Stay), DC Function, Long Stay Hospitalization, and SNF WS PPR Measures

We proposed to adopt the Nursing Staff Turnover measure beginning with the FY 2026 program year; the Falls with Major Injury (Long-Stay), Long Stay Hospitalization, and DC Function measures beginning with the FY 2027 program year; and the SNF WS PPR measure beginning with the FY 2028 program year. Therefore, to meet the requirements at section 1888(h)(1)(C)(i) of the Act, we also proposed to adopt case minimums for those proposed measures.

For the Nursing Staff Turnover measure, we proposed that SNFs must have a minimum of 1 eligible stay during the 1-year performance period and at least 5 eligible nursing staff (RNs, LPNs, and nurse aides) during the 3 quarters of PBJ data included in the measure denominator. SNFs must meet both of these requirements in order to be eligible to receive a score on the measure for the applicable program year. We believe this case minimum requirement is appropriate and consistent with the findings of measure testing analyses and the measure specifications. For example, using FY 2021 data, we estimated that 80 percent of SNFs met the 5-eligible nursing staff minimum. In addition, we note that the 1-eligible stay and 5-eligible nursing staff minimums were determined to be appropriate for publicly reporting this measure on the *Care Compare* website.

For the Falls with Major Injury (Long-Stay) measure, we proposed that SNFs must have a minimum of 20 residents in the measure denominator during the 1-year performance period to be eligible to receive a score on the measure for the applicable fiscal program year. We believe this case minimum requirement is appropriate and consistent with the findings of measure testing analyses. For example, using FY 2021 data, we estimated that nearly 96 percent of SNFs met the 20-resident minimum. In addition, testing results indicated that a 20-resident minimum produced moderately reliable measure rates for the purposes of public reporting.[353]

For the Long Stay Hospitalization measure, we proposed that SNFs must have a minimum of 20 eligible stays during the 1-year performance period to be eligible to receive a score on the measure for the applicable fiscal program year. We believe this case minimum requirement is appropriate and consistent with the findings of measure testing analyses. For example, using CY 2021 data, we estimated that approximately 80 percent of SNFs met the 20-eligible stay minimum. In addition, we note that the 20-eligible stay minimum was determined to be appropriate for publicly reporting this measure under the Five-Star Quality Rating System.

For the DC Function measure, we proposed that SNFs must have a minimum of 20 eligible stays during the 1-year performance period in order to be eligible to receive a score on the measure for the applicable fiscal program year. We believe this case minimum requirement is appropriate and consistent with the findings of measure testing analyses. For example, testing results, which used FY 2019 data, found that nearly 84 percent of SNFs met the 20-eligible stay minimum.[354] In addition, those testing results indicated that a 20-eligible stay minimum produced sufficiently reliable measure rates.

For the SNF WS PPR measure, we proposed that SNFs must have a minimum of 25 eligible stays during the 2-year performance period in order to be eligible to receive a score on the measure for the applicable fiscal program year. We believe this case minimum requirement is appropriate and consistent with the findings of measure testing analyses. For example, using FY 2020 through FY 2021 data, we estimated that nearly 91 percent of non-swing bed SNFs met the 25-eligible stay minimum. In addition, testing results indicated that a 25-eligible stay minimum produced sufficiently reliable measure rates.[355]

We believe these case minimum standards for public reporting purposes are also appropriate standards for establishing a case minimum for these measures under the SNF VBP Program. We also believe these case minimum requirements support our objective, which is to establish case minimums that appropriately balance quality measure reliability with our continuing desire to score as many SNFs as possible on these measures.

We solicited public comment on our proposal to adopt case minimums for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), Long Stay Hospitalization, DC Function, and SNF WS PPR measures.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed case minimums during a performance period for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, Long Stay Hospitalization, and SNF WS PPR measures based on the rationale that the proposed case minimums are appropriate and consistent with measure testing analyses and appropriately balance quality measure reliability with the desire to score as many SNFs as possible on these measures, which is further detailed in section VII.E.2. of the proposed rule (88 FR 21379 through 21380).

Response: We thank the commenters for their support. We agree that these case minimums are consistent with the findings of the measure testing analyses we referenced in section VII.E.2. of the proposed rule (88 FR 21379 through 21380), and support our objective, which is to establish case minimums that appropriately balance quality measure reliability with our continuing desire to score as many SNFs as possible on these measures.

[353] *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[354] *Discharge Function Score for Skilled Nursing Facilities (SNFs) Technical Report,* which is available on the SNF Quality Reporting Program Measures and Technical Information web page at *https://www.cms.gov/files/document/snf-discharge-function-score-technical-report-february-2023.pdf.*

[355] *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: One commenter recommended that CMS adopt case minimum requirements that meet a reliability standard of 0.7. This commenter further recommended that CMS could expand the number of SNFs meeting this higher reliability standard by including multiple years in a performance period, adding that more recent years could be weighted more heavily than preceding years.

Response: We believe that the proposed case minimums ensure that SNF VBP measures are sufficiently reliable for purposes of scoring and payment adjustments under the Program. Our testing has also indicated that increasing the case minimum requirements to achieve the reliability standard of 0.7 would result in minimal improvements to a measure's reliability while simultaneously increasing the number of SNFs that would not meet the higher case minimum requirement, which does not align with our goal to ensure as many SNFs as possible have the opportunity to receive a score on a given measure. Therefore, we do not believe it is currently necessary or feasible to adopt case minimum requirements that meet a reliability standard of 0.7.

We acknowledge the commenter's recommendation to increase measure reliability using longer performance periods and baseline periods and agree that this could increase measure reliability. However, we stated our preference in the FY 2016 SNF PPS final rule (80 FR 46422) and the FY 2017 SNF PPS final rule (81 FR 51998 through 51999), to adopt 1-year performance and baseline periods because that length of time typically provides sufficient levels of data accuracy and reliability for scoring performance, while also allowing us to link SNF performance on a measure as closely as possible to the payment year to ensure clear connections between quality measurement and value-based payment. Where appropriate, we have extended the performance periods and baseline periods for purposes of improving individual measure reliability. For example, in section VIII.C.4. of this final rule, we are finalizing 2-year performance periods and baseline periods for the SNF WS PPR measure because our analytical testing found that using 2-years of data improve the measure's statistical reliability relative to one year of data. In finalizing the 2-year performance periods and baseline periods for the SNF WS PPR measure, we believe that we are appropriately balancing measure reliability with recency of data. We intend to continue considering the balance of these factors when proposing performance periods and baseline periods for any future SNF VBP measure.

After consideration of public comments, we are finalizing the case minimums for the Nursing Staff Turnover, Falls with Major Injury (Long-Stay), Long Stay Hospitalization, DC Function, and SNF WS PPR measures.

c. FY 2026 Measure Minimum

In the FY 2023 SNF PPS final rule (87 FR 47587), we finalized the measure minimum for the FY 2026 program year. Specifically, we finalized that for the FY 2026 program year, SNFs must report the minimum number of cases for two of the three measures during the applicable performance period to receive a SNF Performance Score and value-based incentive payment.

We proposed to adopt an additional measure for the FY 2026 program year: Nursing Staff Turnover measure, which means the FY 2026 SNF VBP measure set will consist of a total of four measures. Although we proposed the Nursing Staff Turnover measure beginning with the FY 2026 program year, which will increase the total number of measures applicable in FY 2026, we believe that our previously finalized minimum of two measures for FY 2026 remains sufficient because if we required a minimum of three or four measures, all swing-bed facilities would be excluded from the Program. Two of the four measures that will be included in the FY 2026 program year are PBJ-based measures. Since swing-bed facilities do not submit PBJ data, those facilities will not meet the measure minimum of reporting three or four measures to the Program. Therefore, to ensure swing-bed facilities continue to have the opportunity to be included in the Program, we did not propose to update the measure minimum for the FY 2026 program year. SNFs must report the minimum number of cases for two of the four measures during the performance period to be included in the FY 2026 program year.

While we did not propose any changes to the measure minimum for FY 2026, we did receive one comment. The following is a summary of the comment and our response.

Comment: One commenter supported the measure minimum for FY 2026.

Response: We thank the commenter for their support of the measure minimum for FY 2026.

d. Updates to the FY 2027 Measure Minimum

In the FY 2023 SNF PPS final rule (87 FR 47587), we finalized the measure minimum for the FY 2027 program year. Specifically, we finalized that for the FY 2027 program year, SNFs must report the minimum number of cases for three of the four measures during the performance period to receive a SNF Performance Score and value-based incentive payment.

In addition to the Nursing Staff Turnover measure beginning with the FY 2026 program year, we also proposed to adopt three additional measures beginning with the FY 2027 program year: Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures. Therefore, the FY 2027 SNF VBP measure set will consist of a total of eight measures. Given the changes to the number of measures applicable in FY 2027, we also proposed to update the measure minimum for the FY 2027 program year.

Specifically, we proposed that for the FY 2027 program year, SNFs must report the minimum number of cases for four of the eight measures during the performance period to receive a SNF Performance Score and value-based incentive payment. SNFs that do not meet these minimum requirements will be excluded from the FY 2027 program and will receive their adjusted Federal per diem rate for that fiscal year. Under these measure minimum requirements, we estimate that approximately 8 percent of SNFs would be excluded from the FY 2027 Program. We found that increasing the measure minimum requirement from three to four measures out of a total of eight measures would cause the number of SNFs excluded from the Program to increase from approximately 3 percent to 8 percent of SNFs for FY 2027. However, the measure minimum requirement that we finalized for FY 2027 in the FY 2023 SNF PPS final rule (87 FR 47587), which was based on a measure set of four measures, excluded approximately 16 percent of SNFs. We also found that increasing the measure minimum requirement would have little effect on the percentage of SNFs that would receive a net-positive incentive payment multiplier (IPM) of the overall distribution of IPMs. Based on these testing results, we believe the updates to the measure minimum for FY 2027 aligns with our desire to ensure that as many SNFs as possible can receive a reliable SNF Performance Score and value-based incentive payment.

We solicited public comment on our proposal to update the measure minimum for the FY 2027 SNF VBP program year.

We received public comments on this proposal. The following is a summary of

the comments we received and our responses.

Comment: One commenter supported the proposed FY 2027 measure minimum.

Response: We thank the commenter for their support of the updated measure minimum for FY 2027.

After consideration of public comments, we are finalizing the update to the measure minimum for the FY 2027 SNF VBP program year.

3. Application of the SNF VBP Scoring Methodology to Proposed Measures

a. Background

In the FY 2023 SNF PPS final rule (87 FR 47588 through 47590), we finalized several updates to the scoring methodology for the SNF VBP Program beginning with the FY 2026 program year. We finalized a measure-level scoring policy such that SNFs have the opportunity to earn a maximum of 10 points on each measure for achievement, and a maximum of nine points on each measure for improvement. The higher of these two scores will then be the SNF's score for each measure and used to calculate the SNF Performance Score, except if the SNF does not meet the case minimum for a given measure during the applicable baseline period, in which case that SNF will only be scored on achievement for that measure. We also finalized a normalization policy such that we will calculate a raw point total for each SNF by adding up that SNF's score on each of the measures applicable for the given program year. We will then normalize the raw point totals such that the SNF Performance Score is reflected on a 100-point scale.

We proposed to adopt the Nursing Staff Turnover measure beginning with the FY 2026 program year; and the Falls with Major Injury (Long-Stay), Long Stay Hospitalization, and DC Function measures beginning with the FY 2027 program year. To accommodate those measures in our scoring methodology, we proposed to adjust our scoring methodology for the FY 2026 and FY 2027 program years, which we discuss in the next section.

We also note that we proposed to replace the SNFRM with the SNF WS PPR measure beginning with the FY 2028 program year, which will not affect the total number of measures applicable in the Program for FY 2028. We intend to address the FY 2028 performance scoring methodology in future rulemaking.

b. FY 2026 Performance Scoring

We proposed the Nursing Staff Turnover measure beginning with the FY 2026 program year, and therefore, the FY 2026 program year measure set will include four measures (SNFRM, SNF HAI, Total Nurse Staffing, and Nursing Staff Turnover measures).

We proposed to apply our previously finalized scoring methodology, which is codified at § 413.338(e) of our regulations, to the Nursing Staff Turnover measure. Specifically, we will award up to 10 points based on achievement, and up to nine points based on improvement, so long as the SNF meets the case minimum for the measure. The higher of these two scores will be the SNF's score for the measure for FY 2026, except in the instance that the SNF does not meet the case minimum for the measure during the applicable baseline period, in which case that SNF will only be scored on achievement for the measure.

As previously finalized, we will then add the score for each of the four measures for which the SNF met the case minimum to get the raw point total. The maximum raw point total for the FY 2026 program year will be 40 points. We will then normalize each SNF's raw point total, based on the number of measures for which that SNF met the case minimum, to get a SNF Performance Score that is on a 100-point scale using our previously finalized normalization policy. We will only award a SNF Performance Score to SNFs that meet the measure minimum for FY 2026.

We solicited public comment on our proposal to apply our previously finalized scoring methodology to the Nursing Staff Turnover measure beginning with the FY 2026 SNF VBP program year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter, while supporting the FY 2026 performance scoring methodology proposal, disagrees with the using the mean of the top decile of SNFs during the baseline period as the benchmark performance standard.

Response: In the FY 2017 SNF PPS final rule (81 FR 51996 through 51997) we stated that our finalized definition of the benchmark represents a demonstrably high but achievable standard of excellence for all SNFs. We refer readers to that final rule for additional details on that policy. We continue to believe that our definition of the benchmark is appropriate for incentivizing high-quality care across SNFs.

Comment: One commenter opposed the FY 2026 performance scoring proposal and recommended that CMS score SNFs on achievement only.

Response: We disagree with the recommendation to score SNFs on achievement only as we are required under section 1888(h)(3)(B) of the Act to include levels of achievement and improvement in the performance standards we use to assess SNF performance under the SNF VBP.

After consideration of public comments, we are finalizing the application of our previously finalized scoring methodology to the Nursing Staff Turnover measure beginning with the FY 2026 SNF VBP program year.

c. FY 2027 Performance Scoring

We proposed the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures beginning with the FY 2027 program year, and therefore, the FY 2027 program year measure set will include eight measures.

Our current scoring methodology is codified at § 413.338(e) of our regulations. Under that scoring methodology, we award up to 10 points for each measure based on achievement, and up to nine points for each measure based on improvement, so long as the SNF meets the case minimum for a given measure. The higher of these two scores is the SNF's score on that measure for FY 2027, except in the instance that the SNF does not meet the case minimum for a given measure during the applicable baseline period, in which case that SNF is only scored on achievement for that measure. As previously finalized, we then sum the scores for each of the eight measures for which the SNF met the case minimum to get the raw measure point total. The maximum raw measure point total for the FY 2027 program year will be 80 points.

We proposed to apply these elements of the scoring methodology to Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures. In addition, and as discussed further in section VIII.E.4. of this final rule, we proposed to adopt a Health Equity Adjustment in which eligible SNFs could earn a maximum of two points for each measure (including all previously finalized and newly proposed measures) if they are a top tier performing SNF, which we proposed to define as a SNF whose score on the measure for the program year falls in the top third of performance (greater than or equal to the 66.67th percentile) on a given measure, and the SNF's resident population during the performance period that applies to the program year includes at least 20 percent of residents

with dual eligibility status (DES). This combination of a SNF's performance and proportion of residents with DES would be used to determine a SNF's Health Equity Adjustment (HEA) bonus points. We would then add the total number of HEA bonus points to the normalized measure point total on a scale from 0 to 100, and that total would be the SNF Performance Score earned by the SNF for the program year. We will only award a SNF Performance Score to SNFs that meet the proposed measure minimum for FY 2027.

We solicited public comment on our proposal to apply our previously finalized scoring methodology to the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures beginning with the FY 2027 SNF VBP program year.

We received public comments on this proposal. The following is a summary of the comments we received on our proposal to apply our previously finalized scoring methodology to the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures and our responses. We provide a summary of comments related to the Health Equity Adjustment, and our responses, in section VIII.E.4. of this final rule.

Comment: A few commenters supported the proposal to apply the previously finalized scoring methodology to the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures beginning with the FY 2027 program year noting that these changes are needed to accommodate the new quality measures in the SNF VBP Program scoring methodology.

Response: We thank the commenters for their support. We agree that applying our scoring methodology to these measures will incentivize high-quality care across all SNFs.

Comment: One commenter, while supporting the FY 2027 performance scoring methodology proposal, disagrees with the using the mean of the top decile of SNFs during the baseline period as the benchmark performance standard.

Response: In the FY 2017 SNF PPS final rule (81 FR 51996 through 51997) we stated that our finalized definition of the benchmark represents a demonstrably high but achievable standard of excellence for all SNFs. We refer readers to that final rule for additional details on that policy. We continue to believe that our definition of the benchmark is appropriate for incentivizing high-quality care across SNFs.

After consideration of public comments, we are finalizing our proposal to apply our previously finalized scoring methodology to the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures beginning with the FY 2027 SNF VBP program year.

4. Incorporating Health Equity Into the SNF VBP Program Scoring Methodology Beginning With the FY 2027 Program Year

a. Background

Significant and persistent inequities in health outcomes exist in the U.S. Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) communities; living in a rural area; being a member of a religious minority; being near or below the poverty level; or being dually enrolled in Medicare and Medicaid, is often associated with worse health outcomes.[356] [357] [358] [359] [360] [361] [362] [363] [364]

Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, (January 20, 2021) defines ''equity'' as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, queer, [and intersex] (LGBTQ[I] +);[365] persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality'' (86 FR 7009). CMS defines ''health equity'' as the ''attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [366]

Advancing health equity is a key pillar of our strategic vision,[367] and we are working to advance health equity by designing, implementing, and operationalizing policies and programs aimed at identifying and reducing health disparities. This includes the CMS Mapping Medicare Disparities Tool,[368] the CMS Innovation Center's Accountable Health Communities Model,[369] the CMS Disparity Methods stratified reporting program,[370] the collection of standardized patient assessment data elements in the post-

[356] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and 30 day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. *British Medical Journal,* 346.

[357] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. *New England Journal of Medicine,* 371(24):2298–2308.

[358] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. *Health Affairs,* 40(2): 307–316.

[359] Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. *Rural Health Research Recap. https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[360] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[361] Vu, M. et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B.

[362] Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians Health Psychol. 2016 Apr; 35(4): 351–355.

[363] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. *medRxiv.* 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327.

[364] Sorbero, M.E., A.M. Kranz, K.E. Bouskill, R. Ross, A.I. Palimaru, and A. Meyer. 2018. Addressing social determinants of health needs of dually enrolled beneficiaries in Medicare Advantage plans: Findings from interviews and case studies. RAND Corporation. Available at *https://www.rand.org/pubs/research_reports/RR2634.html* (accessed December 8, 2022).

[365] We note that the original, cited definition only stipulates, ''LGBTQ+'', however, HHS and the White House now recognize individuals who are intersex/have intersex traits. Therefore, we have updated the term to reflect these changes.

[366] CMS Strategic Plan Pillar: Health Equity. (2022). *https://www.cms.gov/files/document/health-equity-fact-sheet.pdf.*

[367] CMS Strategic Vision. (2022). *https://www.cms.gov/cms-strategic-plan.*

[368] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[369] *https://innovation.cms.gov/innovation-models/ahcm.*

[370] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

acute care setting,[371] and health equity program adjustments like the Medicare Shared Savings Program's recently adopted health equity adjustment for Accountable Care Organizations that report all-payer eCQMs/MIPS CQMs (87 FR 69838 through 69857). Further, the 2022–2032 CMS Framework for Health Equity outlines CMS' priorities to advance health equity, expand coverage, and improve health outcomes for the more than 170 million individuals supported by CMS programs.[372] We also recently updated the CMS National Quality Strategy (NQS), which includes advancing health equity as one of eight strategic goals.[373] As we continue to leverage our programs to improve quality of care, we note it is important to implement strategies that ''create aligned incentives that drive providers to improve health outcomes for all beneficiaries.'' [374]

Prioritizing the achievement of health equity is essential in the SNF VBP Program because disparities in SNFs appear to be widespread, from admissions to quality of care to nurse staffing and turnover.[375] [376] In the 2016 Report to Congress, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) reported that individuals with social risk factors, such as dual eligibility status, had worse outcomes and were more likely to be cared for by lower-quality SNFs.[377] Individuals with dual eligibility status (DES) are those who are eligible for both Medicare and Medicaid coverage. Individuals with DES are more likely to have disabilities or functional impairments, more likely to be medically complex, more likely to have greater social needs, and have a greater risk of negative health outcomes compared to individuals without DES.[378] They are also more likely to be admitted to SNFs that have lower staffing levels, have a higher share of residents who are enrolled in Medicaid in their total resident population, and experience resource constraints.[379] In addition, studies have found that DES is an important predictor of admission to a low-quality SNF.[380] All of these factors indicate that individuals with DES represent an underserved population that is more clinically complex, has greater social needs and is more often admitted to lower-resourced SNFs than those without DES. This presents significant challenges to provide quality care to patients with greater resource-intensive needs by providers that may have fewer resources, as effectively implementing quality improvement initiatives requires time, money, staff, and technology.[381] [382] [383] [384] As a result, competitive programs, like the current SNF VBP Program, may place some SNFs that serve this underserved population at a disadvantage.

In the FY 2023 SNF PPS proposed rule (87 FR 22789), we requested public comment on policy changes that we should consider on the topic of health equity. In the FY 2023 SNF PPS final rule (87 FR 47596 through 47597), we provided a detailed summary of the feedback we received on this topic. Commenters overwhelmingly supported our commitment to advancing health equity for SNF residents, with some suggesting that we examine factors that may lead to care inequities. One commenter suggested we adopt risk adjustment or incentive payments for SNFs that admit individuals that other SNFs will not admit. Another commenter recommended pairing clinical data measures with social risk metrics to help providers deliver more comprehensive care. Overall, commenters were interested in understanding where disparities may exist and wanted us to work with SNFs and other interested parties to understand the greatest needs in achieving health equity to ensure any revisions to the Program could be implemented with minimal data burden. We considered all the comments we received as we developed our Health Equity Adjustment for the SNF VBP Program described below.

We believe that SNFs and providers across all settings can consistently perform well even when caring for a high proportion of individuals who are underserved,[385] and, with the right program components, VBP programs can create meaningful incentives for SNFs that serve a high proportion of individuals who are underserved to

[371] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/-IMPACT-Act-Standardized-Patient-Assessment-Data-Elements.*

[372] CMS Framework for Health Equity (2022). *https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.*

[373] CMS National Quality Strategy (2022). Centers for Medicare and Medicaid Services. *https://www.cms.gov/files/document/cms-national-quality-strategy-fact-sheet.pdf.*

[374] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[375] Rivera-Hernandez, M., Rahman, M., Mor, V., & Trivedi, A.N. (2019). Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. *Journal of the American Geriatrics Society,* 67(8), 1672–1679. *https://doi.org/10.1111/jgs.15960.*

[376] Konetzka, R., Yan, K., & Werner, R.M. (2021). Two Decades of Nursing Home Compare: What Have We Learned? *Medical Care Research and Review,* 78(4), 295–310. *https://doi.org/10.1177/1077558720931652.*

[377] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

[378] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032.*

[379] Rahman, M., Grabowski, D.C., Gozalo, P.L., Thomas, K.S., & Mor, V. (2014). Are Dual Eligibles Admitted to Poorer Quality Skilled Nursing Facilities? *Health Services Research,* 49(3), 798–817. *https://doi.org/10.1111/1475-6773.12142.*

[380] Zuckerman, R.B., Wu, S., Chen, L.M., Joynt Maddox, K.E., Sheingold, S.H., & Epstein, A.M. (2019). The Five-Star Skilled Nursing Facility Rating System and Care of Disadvantaged Populations. *Journal of the American Geriatrics Society,* 67(1), 108–114. *https://doi.org/10.1111/jgs.15629.*

[381] Reidt, S.L., Holtan, H.S., Larson, T.A., Thompson, B., Kerzner, L.J., Salvatore, T.M., & Adam, T.J. (2016). Interprofessional Collaboration to Improve Discharge from Skilled Nursing Facility to Home: Preliminary Data on Postdischarge Hospitalizations and Emergency Department Visits. *Journal of the American Geriatrics Society, 64*(9), 1895–1899. *https://doi.org/10.1111/jgs.14258.*

[382] Au, Y., Holbrook, M., Skeens, A., Painter, J., McBurney, J., Cassata, A., & Wang, S.C. (2019). Improving the quality of pressure ulcer management in a skilled nursing facility. *International Wound Journal, 16*(2), 550–555. *https://doi.org/10.1111/iwj.13112.*

[383] Berkowitz, R.E., Fang, Z., Helfand, B.K.I., Jones, R.N., Schreiber, R., & Paasche-Orlow, M.K. (2013). Project ReEngineered Discharge (RED) Lowers Hospital Readmissions of Patients Discharged From a Skilled Nursing Facility. *Journal of the American Medical Directors Association, 14*(10), 736–740. *https://doi.org/10.1016/j.jamda.2013.03.004.*

[384] Chisholm, L., Zhang, N.J., Hyer, K., Pradhan, R., Unruh, L., & Lin, F.-C. (2018). Culture Change in Nursing Homes: What Is the Role of Nursing Home Resources? *INQUIRY: The Journal of Health Care Organization, Provision, and Financing, 55,* 0046958018787043. *https://doi.org/10.1177/0046958018787043.*

[385] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

deliver high quality care.[386] [387] [388] [389] [390] [391] We believe updating the scoring methodology, as detailed in the following sections, would appropriately measure performance and create these meaningful incentives for SNFs that care for a high proportions of residents with DES.

b. Health Equity Adjustment Summary

Section 1888(h)(4)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each SNF based on performance standards established under section 1888(h)(3) of the Act with respect to the measures applied under section 1888(h)(2) of the Act. To further align with our goals to achieve health equity, address health disparities, and assess SNF performance more accurately and completely under the SNF VBP Program, we proposed to apply an adjustment that will be added to the normalized sum of a SNF's measure points on SNF VBP Program measures. As described previously, residents with DES are an underserved population that is clinically complex, has significant social needs and is more frequently admitted to SNFs that have larger populations of Medicaid residents and fewer resources than SNFs that do not care for individuals with DES.[392] [393] [394] These lower-resourced SNFs are less likely to receive positive payment adjustments, which is a considerable limitation of the current SNF VBP program's ability to incentivize equitable care.[395] Careful consideration must be taken to modify the Program in a way that addresses this issue and ensures that we provide appropriate rewards and incentives to all SNFs, including those that serve residents with DES. The goal of this Health Equity Adjustment is to not only appropriately measure performance by rewarding SNFs that overcome the challenges of caring for higher proportions of SNF residents with DES but also to incentivize those who have not achieved such high-quality care to work towards improvement. We believe this Health Equity Adjustment incentivizes high-quality care across all SNFs. We also believe this scoring change, through the adoption of an adjustment designed to award points based on the quality of care provided and the proportion of residents with DES, is consistent with our strategy to advance health equity.[396]

The Health Equity Adjustment (HEA) will be calculated using a methodology that considers both the SNF's performance on the SNF VBP Program measures, and the proportion of residents with DES out of the total resident population in a given program year at each SNF. To be eligible to receive HEA bonus points, a SNF's performance will need to meet or exceed a certain threshold and its resident population during the applicable performance period for the program year will have to include at least 20 percent of residents with DES. Thus, SNFs that perform well on quality measures and serve a higher proportion of SNF residents with DES will receive a larger adjustment. We provide the HEA calculation methodology in section VIII.E.4.d. of this final rule. By providing this HEA to SNFs that serve higher proportions of SNF residents with DES and that perform well on quality measures, we believe we can appropriately recognize the resource intensity expended to achieve high performance on quality measures by SNFs that serve a high proportion of SNF residents with DES, while also mitigating the worse health outcomes experienced by underserved populations through incentivizing better care across all SNFs.

An analysis of payment from October 2018 for the SNF VBP Program found that SNFs that served higher proportions of Medicaid residents were less likely to receive positive payment adjustments. As noted previously, residents with DES are more likely to be admitted to SNFs with higher proportions of Medicaid residents [397] suggesting that SNFs serving higher proportions of SNF residents with DES face challenges in utilizing their limited resources to improve the quality of care for their complex residents.[398] Thus, we aimed to adjust the current program scoring methodology to ensure that all SNF residents, including those with DES, receive high-quality care. We conducted an analysis utilizing FY 2018 through FY 2021 measure data for our previously finalized and newly proposed measures, including a simulation of performance on all 8 measures for the FY 2027 Program, and found that the HEA significantly increased the proportion of SNFs with high proportions of SNF residents with DES that received a positive value-based incentive payment adjustment indicating that this approach would modify the SNF VBP Program in the way it is intended.

We proposed to call this adjustment the Health Equity Adjustment (HEA)

[386] Crook, H.L., Zheng, J., Bleser, W.K., Whitaker, R.G., Masand, J., & Saunders, R.S. (2021). *How Are Payment Reforms Addressing Social Determinants of Health? Policy Implications and Next Steps.* Milbank Memorial Fund, Duke Margolis Center for Health Policy. *https://www.milbank.org/wp-content/uploads/2021/02/Duke-SDOH-and-VBP-Issue-Brief_v3.pdf.*

[387] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope),* 38(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032.*

[388] Konetzka, R., Yan, K., & Werner, R.M. (2021). Two Decades of Nursing Home Compare: What Have We Learned? *Medical Care Research and Review,* 78(4), 295–310. *https://doi.org/10.1177/1077558720931652.*

[389] Weech-Maldonado, R., Pradhan, R., Dayama, N., Lord, J., & Gupta, S. (2019). Nursing Home Quality and Financial Performance: Is There a Business Case for Quality? *Inquiry: A Journal of Medical Care Organization, Provision and Financing,* 56, 46958018825191. *https://doi.org/10.1177/0046958018825191.*

[390] Rivera-Hernandez, M., Rahman, M., Mukamel, D., Mor, V., & Trivedi, A. (2019). Quality of Post-Acute Care in Skilled Nursing Facilities That Disproportionately Serve Black and Hispanic Patients. *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences,* 74(5). *https://doi.org/10.1093/gerona/gly089.*

[391] Burke, R.E., Xu, Y., & Rose, L. (2022). Skilled Nursing Facility Performance and Readmission Rates Under Value-Based Purchasing. *JAMA Network Open,* 5(2), e220721. *https://doi.org/10.1001/jamanetworkopen.2022.0721.*

[392] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032.*

[393] Rahman, M., Grabowski, D.C., Gozalo, P.L., Thomas, K.S., & Mor, V. (2014). Are Dual Eligibles Admitted to Poorer Quality Skilled Nursing Facilities? *Health Services Research,* 49(3), 798–817. *https://doi.org/10.1111/1475-6773.12142.*

[394] Zuckerman, R.B., Wu, S., Chen, L.M., Joynt Maddox, K.E., Sheingold, S.H., & Epstein, A.M. (2019). The Five-Star Skilled Nursing Facility Rating System and Care of Disadvantaged Populations. *Journal of the American Geriatrics Society,* 67(1), 108–114. *https://doi.org/10.1111/jgs.15629.*

[395] Hefele JG, Wang XJ, Lim E. Fewer Bonuses, More Penalties at Skilled Nursing Facilities Serving Vulnerable Populations. *Health Aff (Millwood).* 2019;38(7):1127–1131. doi:10.1377/hlthaff.2018.05393.

[396] Centers for Medicare & Medicaid Services. (2022) CMS Outlines Strategy to Advance Health Equity, Challenges Industry Leaders to Address Systemic Inequities. Available at *https://www.cms.gov/newsroom/press-releases/cms-outlines-strategy-advance-health-equity-challenges-industry-leaders-address-systemic-inequities#:~:text=In%20effort%20to%20address%20systemic%20inequities%20across%20the,Medicare%2C%20Medicaid%20or%20Marketplace%20coverage%2C%20need%20to%20thrive.*

[397] Rahman, M., Grabowski, D.C., Gozalo, P.L., Thomas, K.S., & Mor, V. (2014). Are Dual Eligibles Admitted to Poorer Quality Skilled Nursing Facilities? *Health Services Research,* 49(3), 798–817. *ws://doi.org/10.1111/1475-6773.12142.*

[398] Hefele JG, Wang XJ, Lim E. Fewer Bonuses, More Penalties at Skilled Nursing Facilities Serving Vulnerable Populations. *Health Aff (Millwood).* 2019;38(7):1127–1131. doi:10.1377/hlthaff.2018.05393.

and to adopt it beginning with the FY 2027 program year.

c. Health Equity Adjustment Beginning With the FY 2027 SNF VBP Program Year

We proposed to define the term ''underserved population'' as residents with DES for purposes of this HEA. DES has been established in the literature, including research specifically looking at SNFs,[399] [400] and has been found to be an important factor that impacts pay for performance and other quality programs.[401] [402] In addition, DES is currently utilized in the Hospital Readmissions Reduction Program.

The Medicare Shared Savings Program recently adopted a health equity adjustment for Accountable Care Organizations that report all-payer eCQMs/MIPS CQMs, are high-performing on quality, and serve a large proportion of underserved beneficiaries, as defined by dual-eligibility/enrollment in the Medicare Part D low income subsidy (LIS) (meaning the individual is enrolled in a Part D plan and receives LIS) and an Area Deprivation Index (ADI) score of 85 or above, as detailed in the CY 2023 PFS final rule (87 FR 69838 through 69857). At this time, for the SNF VBP Program's HEA, we believe that it is preferable to use DES to identify SNF residents who are underserved. We also explored alternative indicators to identify populations that are underserved for purposes of this HEA, such as a resident's eligibility for the Medicare Part D Low-Income Subsidy (LIS) program or whether the resident lives in an area with high deprivation, as measured by the Area Deprivation Index (ADI), however, we determined that for the HEA, utilizing residents with DES to identify underserved populations will best serve the goals of the adjustment. Individuals who are eligible for the LIS program have incomes up to 150 percent of the Federal poverty level.[403] Utilizing residents who are eligible for the LIS program would include most residents with DES, as well as additional residents who may be underserved; however, the data on the LIS program are only available for those enrolled in Medicare Part D, which may limit its effectiveness, and it is not uniform across both States and territories. Further, those eligible for the LIS program have not been studied extensively in the SNF setting and the effect of using those eligible for the LIS program to determine a SNF's underserved population has also not been studied extensively. Geographic-based or neighborhood-level economic indices, such as the ADI, have been utilized to look at characteristics of healthcare facilities in low-resourced areas and could be used as a proxy for negative health outcomes due to medical and social risk factors.[404] [405] ADI appears to be an important predictor of poor health outcomes, even when adjusting for individual characteristics, suggesting neighborhood or geography may play an even more important role in health than individual characteristics.[406] [407] However, there is not much literature or analysis that has been conducted linking these indices to negative health outcomes specifically in the SNF setting. Therefore, we proposed to only use DES data at this time to identify SNF residents who are underserved for this HEA, given that the DES data are readily available, are evidenced based in the SNF setting, and are already used in the Hospital Readmissions Reduction Program. We intend to consider how to best incorporate the LIS, ADI, and other indicators to identify those who are underserved in future health equity adjustment proposals for the SNF VBP Program as more research is made available. We solicited public comment, and provide a summary of the comments we received, on the potential future use of these additional indicators in section VIII.E.5 of this final rule. We provide additional detail on how we will calculate SNF residents with DES for the purpose of this adjustment later in this section.

In order to calculate the HEA, we first proposed to assign each SNF 2 points for each measure for which it is a top tier performing SNF. We proposed to define a top tier performing SNF as a SNF whose performance during the program year is in the top third (greater than or equal to the 66.67th percentile) of the performance of all SNFs on the measure during the same program year. Each measure will be assessed independently such that a SNF that is a top tier performing SNF for one measure will be assigned 2 points for that measure even if they are not a top tier performing SNF for any other measure. Similarly, if a SNF is a top tier performing SNF for all measures, that SNF will be assigned 2 points for all measures.

We also proposed to assign a measure performance scaler for each SNF that will be equal to the total number of assigned HEA points that the SNF earns on all measures as a result of its performance. Under this approach, for the FY 2027 program year, a SNF will receive a maximum measure performance scaler of 16 if the SNF is a top tier performing SNF on all 8 measures for that program year. As described in more detail in the following paragraph and in section VIII.E.4.e of this final rule, we decided on assigning a maximum point value of 2 points for each measure because we believe that it provides an appropriate incentive to top tier performing SNFs that serve a high proportion of SNF residents with DES to continue their quality efforts, as well as an incentive for all SNFs that serve SNF residents with DES to improve their quality.

Based on our calculation of measure data from FY 2018 through FY 2021, the average SNF Performance Score for SNFs in the top third of performance that care for high proportions of residents with DES (SNFs with proportions of residents with DES in the top third) is 8.4 points lower than the SNF Performance Score for SNFs in the top third of performance that do not

[399] Rahman, M., Grabowski, D.C., Gozalo, P.L., Thomas, K.S., & Mor, V. (2014). Are Dual Eligibles Admitted to Poorer Quality Skilled Nursing Facilities? *Health Services Research,* 49(3), 798–817. *https://doi.org/10.1111/1475-6773.12142.*

[400] Zuckerman, R.B., Wu, S., Chen, L.M., Joynt Maddox, K.E., Sheingold, S.H., & Epstein, A.M. (2019). The Five-Star Skilled Nursing Facility Rating System and Care of Disadvantaged Populations. *Journal of the American Geriatrics Society,* 67(1), 108–114. *https://doi.org/10.1111/jgs.15629.*

[401] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

[402] Zuckerman, R.B., Wu, S., Chen, L.M., Joynt Maddox, K.E., Sheingold, S.H., & Epstein, A.M. (2019). The Five-Star Skilled Nursing Facility Rating System and Care of Disadvantaged Populations. *Journal of the American Geriatrics Society,* 67(1), 108–114. *https://doi.org/10.1111/jgs.15629.*

[403] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

[404] The University of Wisconsin Neighborhood Atlas website (*https://www.neighborhoodatlas.medicine.wisc.edu/*).

[405] Falvey, J.R., Hade, E.M., Friedman, S., Deng, R., Jabbour, J., Stone, R.I., & Travers, J.L. (2022). Severe neighborhood deprivation and nursing home staffing in the United States. *Journal of the American Geriatrics Society. https://doi.org/10.1111/jgs.17990.*

[406] Chamberlain, A.M., Finney Rutten, L.J., Wilson, P.M., Fan, C., Boyd, C.M., Jacobson, D.J., Rocca, W.A., & St. Sauver, J.L. (2020). Neighborhood socioeconomic disadvantage is associated with multimorbidity in a geographically-defined community. *BMC Public Health, 20*(1), 13. *https://doi.org/10.1186/s12889-019-8123-0.*

[407] Hu, J., Kind, A.J.H., & Nerenz, D. (2018). Area Deprivation Index (ADI) Predicts Readmission Risk at an Urban Teaching Hospital. *American Journal of Medical Quality: The Official Journal of the American College of Medical Quality, 33*(5), 493–501. *https://doi.org/10.1177/1062860617753063.*

care for high proportions of residents with DES (40.8 for high performing SNFs with high proportions of residents with DES and 49.2 for all other high performing SNFs). Allowing for a maximum measure performance scaler of 16 for the FY 2027 program year will provide an opportunity for top tier performing SNFs that treat a high proportion of SNF residents with DES to close this gap. We also considered assigning 3 points for each measure to calculate the measure performance scaler. However, we determined that the maximum measure performance scaler a SNF could earn based on the assignment of 3 points per measure, 24 points, would exceed the number of points that many SNFs receive for their SNF Performance Score based on all Program measures, which diminishes the intent of the HEA as a bonus. We further discuss this option in section VIII.E.4.e of this final rule. We also considered assigning a point value of 2 to SNFs in the middle third of performance (SNFs whose performance falls between the 33.33rd percentile and 66.67th percentile in performance) and assigning a point value of 4 to top tier performing SNFs for each measure to align with the Medicare Shared Savings Program's health equity adjustment (87 FR 69843 through 69845). This approach would provide a greater number of SNFs the opportunity to benefit from the adjustment. However, in the SNF VBP Program, this approach could reduce the size of the payment adjustment available to SNFs whose performance is in the top tier, reducing the incentives to improve and deviating considerably from the primary goal of the Program to appropriately assess performance and reward high quality performance among SNFs that care for high proportions of residents with DES.

We proposed to define the term ''underserved multiplier'' for a SNF as the number representing the SNF's proportion of residents with DES out of its total resident population in the applicable program year, translated using a logistic exchange function. Due to the structure of the logistic exchange function, those SNFs with lower proportions of residents with DES have smaller underserved multipliers than their actual proportion of residents with DES and those SNFs with higher proportions of SNF residents with DES have underserved multipliers higher than their proportion of SNF residents with DES. The specific logistic function used to translate the SNF's proportion of residents with DES is described in section VIII.E.4.d. of this final rule. We proposed to define the total resident population at each SNF as Medicare beneficiaries identified from the SNF's Part A claims during the performance period of the 1-year measures. We proposed to define residents with DES, for purposes of the HEA, as the percentage of Medicare SNF residents who are also eligible for Medicaid. We proposed to assign DES for any Medicare beneficiary who was deemed by Medicaid agencies to be eligible to receive Medicaid benefits for any month during the performance period of the 1-year measures. For example, during the FY 2027 program year, we will calculate the proportion of residents with DES during any month of FY 2025 (October 1, 2024 through September 30, 2025), which is the performance period for the FY 2027 program year's 1-year measures. Similarly, a SNF's total resident population of Medicare beneficiaries identified from the SNF's Part A claims will be calculated from the SNF's Part A claims during FY 2025. Data on DES is sourced from the State Medicare Modernization Act (MMA) file of dually eligible beneficiaries, which each of the 50 States and the District of Columbia submit to CMS at least monthly. This file is utilized to deem individuals with DES automatically eligible for the Medicare Part D Low Income Subsidy, as well as other CMS program needs and thus can be considered the gold standard for determining DES. We note that this is the same file used for determining DES in the Hospital Readmissions Reduction Program. Additional details on this file can be found on the CMS website at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/StateMMAFile* and at the Research Data Assistance Center website at *https://resdac.org/cms-data/variables/monthly-medicare-medicaid-dual-eligibility-code-january*.

We proposed to calculate an underserved multiplier for a SNF if that SNF's proportion of residents with DES out of its total resident population during the applicable performance period of the 1-year measures is at least 20 percent. Imposing a floor of 20 percent for the underserved multiplier for a SNF to be eligible to receive HEA bonus points, reinforces that the adjustment is intended to appropriately measure performance by rewarding SNFs that are serving higher proportions of SNF residents with DES while also achieving high levels of quality performance. We describe this 20 percent floor in further detail in section VIII.E.4.d. of this final rule. Lastly, we proposed to define HEA bonus points for a SNF as the product of the SNF's measure performance scaler and the SNF's underserved multiplier. The HEA bonus points will then be added to the normalized sum of all points a SNF is awarded for each measure.

Through the HEA bonus points, we seek to improve outcomes by providing incentives to SNFs to strive for high performance across measures, as well as to care for high proportions of residents with DES. The HEA bonus points calculation is purposefully designed to not reward poor quality. Instead, the HEA incentivizes SNFs that care for higher proportions of SNF residents with DES to improve their overall quality of care across the entire SNF population. As described more fully in section VIII.E.4.d. of this final rule, the combination of the measure performance scaler and the underserved multiplier will result in a range of possible HEA bonus points that is designed to give the highest rewards to SNFs caring for a larger proportion of SNF residents with DES and delivering high quality care.

We proposed to amend our regulations at § 413.338(a) to define these new scoring methodology terms, including underserved population, the measure performance scaler, top tier performing SNF, the underserved multiplier, and the HEA bonus points. We also proposed to codify the HEA in our regulations by adding a new paragraph (k) at § 413.338 of our regulations. We solicited public comments on these proposals. We provide a summary of the comments we received, and our responses, later in this section.

d. Alternatives Considered

In developing the HEA, we considered approaches other than providing HEA bonus points to top tier performing SNFs with a high proportion of SNF residents with DES that could be implemented in the SNF VBP Program. More specifically, we considered the addition of risk adjustment to the payment methodology, peer grouping, or providing an opportunity to earn additional improvement points. First, we considered risk adjusting the measures used in the SNF VBP program. Currently, most measures in the SNF VBP Program are risk adjusted for the clinical characteristics of the resident that are included in the calculation of the measure. We do not risk adjust for social risk factors. Although it would require us to respecify the measures and then revisit the pre-rulemaking process for each measure, it is an operationally feasible approach. However, there is a

significant concern around adding additional risk adjustment to the measures in the Program to account for social risk factors. Although additional risk adjustment can help account for factors outside of a SNF's control, such as social risk factors like socioeconomic status,[408] it can also have potential unintended consequences. For instance, in a 2021 Report to Congress on Medicare and the Health Care Delivery System, the Medicare Payment Advisory Commission (MedPAC) recommended against adjusting SNF VBP measures results for social risk factors, stating that those types of adjustments can mask disparities.[409] This would mean that disparities that currently exist would be more challenging to identify in the data, and thus harder for providers or the Program to eliminate. Additionally, in an analysis conducted by ASPE, it did not appear that additional risk adjustment would significantly impact SNF performance in the Program.[410] Thus, we decided against incorporating additional risk adjustment into the SNF VBP Program at this time.

Second, we considered adding a peer grouping component to our scoring methodology, under which we would divide SNFs into groups based on the proportion of residents with DES that a SNF serves. With this peer grouping, different performance standards would then be set for each group, and thus payment adjustments would be made based on the group or strata in which a SNF falls.[411] However, ASPE noted in their second report to congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program that although they support stratifying quality measures by DES to identify disparities, they had concerns that peer grouping could risk setting different standards of care for SNFs caring for underserved populations.[412]

Finally, we considered an approach of adding additional improvement points to the Program. This could be achieved by either providing bonus points to SNFs for measures in which they had significant improvement or by increasing the points available for improvement from 9 points to some higher quantity, such as 15 points. It is important that even poorer performing SNFs be provided incentives to improve as all residents should have the opportunity to receive high quality care, and currently lower performers have the greatest opportunity for improvement. Since SNFs that care for higher proportions of SNF residents with DES tend to have lower SNF Performance Scores compared to SNFs that do not care for higher proportions of SNF residents with DES, this Program adjustment could address health equity by providing lower performing SNFs that care for higher proportions of SNF residents with DES additional incentives to improve the care they provide. However, we had concerns with this approach. First, this approach is not focused specifically on populations that are underserved, and it is unclear whether the additional improvement points available would provide sufficient incentives for SNFs that care for higher proportions of SNF residents with DES to invest the limited resources they have to make the changes necessary to benefit from it. We were also concerned that this change could primarily incentivize poorer performing SNFs that do not care for a higher proportion of SNF residents with DES. Although we aim to incentivize improvement in care for all SNFs, this alternative approach has a significant risk of not meeting the goals of a health equity-focused adjustment in the Program. Therefore, in considering how to modify the existing SNF VBP Program to advance health equity, we believe that rather than utilizing risk adjustment, peer grouping or adjusting the improvement point allocation process, it would be more appropriate to adopt an approach that rewards overall high-quality performance and incentivizes health equity.

In conclusion, we believe the HEA proposal allows us to appropriately measure performance by rewarding SNFs that overcome the challenges of caring for higher proportions of SNF residents with DES and to incentivize those who have not achieved such high-quality care to work towards improvement. As the Program expands beyond one measure, we believe this HEA will support high-quality care for all populations and recognize top tier performing SNFs serving residents with DES.

e. HEA Calculation Steps and Examples

In this section, we outline the calculation steps and provide examples of the determination of HEA bonus points and the application of these HEA bonus points to the normalized sum of a SNF's measure points. These example calculations illustrate possible HEA bonus points resulting from this approach, which accounts for both a SNF's quality performance and its proportion of residents with DES. For each SNF, the HEA bonus points would be calculated according to the following formula:

HEA bonus points = measure performance scaler × underserved multiplier

The calculation of the HEA bonus points will be as follows:

Step One—Calculate the Measure Performance Scaler for Each SNF

We will first calculate a measure performance scaler based on a SNF's score on each of the SNF VBP program measures. We will assign a point value of 2 for each measure where a SNF is a top tier performing SNF on that measure, such that for the FY 2027 program year, a SNF could receive a maximum 16-point measure performance scaler for being a top tier performing SNF for each of the 8 measures. Top tier performance on each measure is calculated by determining the percentile that the SNF falls in based on their score on the measure as compared to the score earned by other SNFs who are eligible to receive a score on the measure. A SNF whose score is greater than or equal to the 66.67th (two-thirds) percentile on a given measure compared to all other SNFs will be considered a top tier performing SNF and will be assigned a point value of 2 for that measure. This is depicted in Table 19 for the FY 2027 program year. We note that if a SNF performs in the bottom two-thirds (less than 66.67th percentile) of performance on all measures, that SNF would be assigned a point value of 0 for each measure, resulting in a measure performance scaler of 0.

As described previously, we proposed to assign to each SNF a point value of 2 for each measure for which it is a top tier performing SNF, and we proposed that the measure performance scaler would be the sum of the point values

[408] *https://mmshub.cms.gov/sites/default/files/Risk-Adjustment-in-Quality-Measurement.pdf.*

[409] MedPAC, 2021 *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf.*

[410] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[411] Chen, A., Ghosh, A., Gwynn, K.B., Newby, C., Henry, T.L., Pearce, J., Fleurant, M., Schmidt, S., Bracey, J., & Jacobs, E.A. (2022). Society of General Internal Medicine Position Statement on Social Risk and Equity in Medicare's Mandatory Value-Based Payment Programs. *Journal of General Internal Medicine, 37*(12), 3178–3187. *https://doi.org/10.1007/s11606-022-07698-9.*

[412] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

assigned to each measure in the SNF VBP Program. We modeled this measure performance scaler after the performance scaler finalized in the Medicare Shared Savings Program's health equity adjustment (87 FR 69843 through 69845) for consistency across CMS programs, although that adjustment allows for a middle performance group as well. However, as described previously, because we aim to specifically target the highest performing SNFs for this adjustment, we are limiting our adjustment to the top third of performers only.

TABLE 19—EXAMPLE OF THE MEASURE PERFORMANCE SCALER ASSIGNED TO SNFS BASED ON PERFORMANCE BY MEASURE

Measure	Example SNF 1		Example SNF 2		Example SNF 3		Example SNF 4	
	Performance group	Value	Performance group	Value	Performance group	Value	Performance group	Value
SNFRM*	Top third	2	Top Third	2	Top Third	2	Bottom Two-Thirds	0
SNF HAI Measure	Top third	2	Top Third	2	Top Third	2	Bottom Two-Thirds	0
Total Nurse Staffing Measure.	Top third	2	Bottom Two-Thirds	0	Bottom Two-Thirds	0	Top Third	2
DTC–PAC SNF Measure.	Top third	2	Top Third	2	Bottom Two-Thirds	0	Bottom Two-Thirds	0
Falls with Major Injury (Long-Stay) Measure**.	Top Third	2	Top Third	2	Bottom Two-Thirds	0	Bottom Two-Thirds	0
DC Function Measure**	Top Third	2	Top Third	2	Top Third	2	Bottom Two-Thirds	0
Long Stay Hospitalization Measure**.	Top Third	2	Top Third	2	Top Third	2	Bottom Two-Thirds	0
Nursing Staff Turnover Measure**.	Top Third	2	Top Third	2	Top Third	2	Bottom Two-Thirds	0
	Measure Performance Scaler.	16	Measure Performance Scaler.	14	Measure Performance Scaler.	10	Measure Performance Scaler.	2

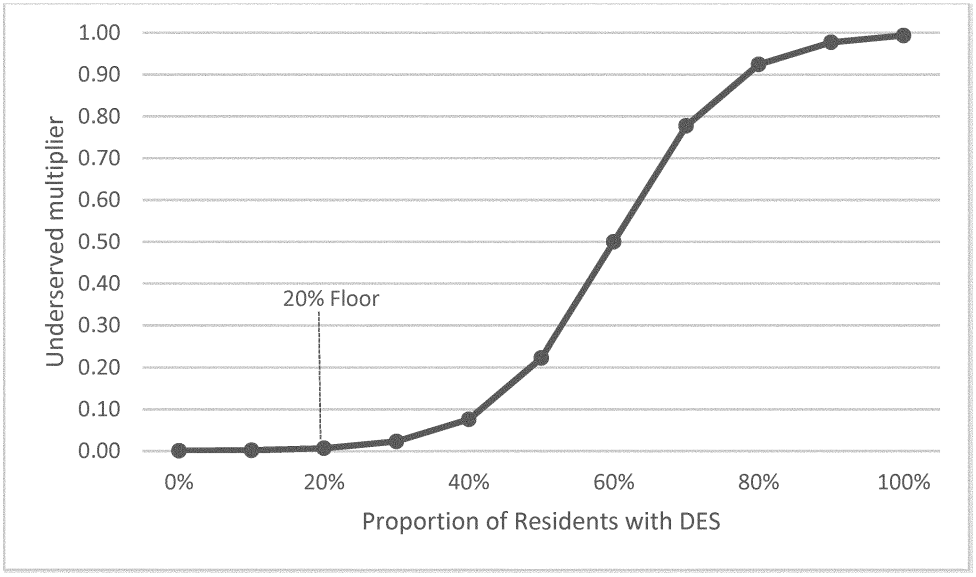
Notes:
*We proposed to replace the SNFRM would be replaced with the SNF WS PPR beginning with the FY 2028 program year.
**We proposed to adopt the Nursing Staff Turnover Measure beginning with the FY 2026 program year and the Falls with Major Injury (Long-Stay) Measure, DC Function Measure, and Long Stay Hospitalization Measure beginning with the FY 2027 program year.

Step Two—Calculate the Underserved Multiplier

We proposed to calculate an underserved multiplier, which, as stated previously, we proposed to define as, for a SNF, the number representing the SNF's proportion of residents with DES out of its total resident population in the applicable program year, translated using a logistic exchange function. As stated previously, the primary goal of the adjustment is to appropriately measure performance by rewarding SNFs that are able to overcome the challenges of caring for high proportions of residents with DES while still providing high quality care. We can also accomplish the goal of this adjustment by utilizing a logistic exchange function to calculate the underserved multiplier, which will provide SNFs who care for the highest proportions of SNF residents with DES with the most HEA bonus points. Thus, we proposed to utilize a logistic exchange function to calculate the underserved multiplier for scoring SNFs such that there would be a lower rate of increase at the beginning and the end of the curve. The formula for the underserved multiplier using a logistic exchange function would be as follows:

$$underserved\ multiplier = \frac{1}{1 + e^{-12.5(percent\ of\ residents\ with\ DES - 0.6)}}$$

Due to the structure of the logistic exchange function, those SNFs with lower proportions of residents with DES have smaller underserved multipliers than their actual proportion of residents with DES and those SNFs with higher proportions of SNF residents with DES have underserved multipliers higher than their proportion of SNF residents with DES. A logistic exchange function assumes a large difference between SNFs treating the most and fewest residents with DES. Therefore, the logistic exchange function provides higher HEA bonus points to SNFs serving greater proportions of SNF residents with DES. For example, as shown in Figure A, if a SNF serves 70 percent of SNF residents with DES, the SNF would receive an underserved multiplier of 0.78.



We proposed that SNFs will receive an underserved multiplier of 0 if the SNF's proportions of SNF residents with DES is less than 20 percent, thereby establishing a ''floor'' on the magnitude of the SNF's underserved population proportion in order for the SNF to be eligible for any HEA bonus points. Because SNFs with proportions of SNF residents with DES below 20 percent receive a value of 0 for their underserved multiplier, any multiplication with the measure performance scaler will be 0 and will lead to those SNFs receiving no HEA bonus points. Imposing a floor of 20 percent for the underserved multiplier for a SNF to be eligible to receive HEA bonus points, reinforces that the adjustment is intended to appropriately measure performance by rewarding SNFs that are serving higher proportions of SNF residents with DES while also achieving high levels of quality performance. We believe this approach is necessary to remain consistent with the goal to reward high quality care specifically among SNFs that care for higher proportions of SNF residents with DES. We anticipate the vast majority of SNFs will be able to earn HEA bonus points despite this floor, and we expect the percent of SNFs meeting the 20 percent floor for the underserved multiplier may increase over time, as existing SNFs seek to expand their resident population to earn HEA bonus points. We also believe that the challenges associated with caring for residents with DES, a complex resident population, will be negligible if 80 percent of a SNF's resident population is not underserved. This 20 percent floor is consistent with the new health equity adjustment for ACOs that report all payer eCQMs/MIPS CQMs, as finalized in the CY 2023 PFS final rule (87 FR 69849 through 69852).

Alternatively, we considered establishing a floor of 60 percent such that all SNFs with proportions of SNF residents with DES below 60 percent would receive an underserved multiplier of 0, and therefore, would not receive any HEA bonus points. Although this would provide a greater value-based incentive payment amount to top tier performing SNFs that serve the highest proportions of SNF residents with DES and thus would support the primary goal of the adjustment, it would also mean SNFs that care for high proportions of SNF residents with DES who likely face similar challenges, albeit to a lesser extent, would receive no adjustment at all.

Step Three—Calculate the HEA Bonus Points

We proposed to calculate the HEA bonus points that apply to a SNF for a program year by multiplying the measure performance scaler by the underserved multiplier. We believe that combining the measure performance scaler and the underserved multiplier to calculate the HEA bonus points allows for us to reward those SNFs with high quality that are also serving high proportions of SNF residents with DES, while incentivizing other SNFs to improve their performance (by a higher measure performance scaler) and serve more SNF residents with DES (by a higher underserved multiplier) in order to earn more HEA bonus points. Table 20 shows examples of how the measure performance scaler and underserved multiplier would be used to calculate the HEA bonus points. It also demonstrates how the logistic exchange function that we proposed to use to calculate the underserved multiplier interacts with the measure performance scaler and results in SNFs serving higher proportion of SNF residents with DES receiving more HEA bonus points. For instance, example SNF 1 with 16 points and a proportion of residents with DES of 50 percent received a measure performance scaler of 16 and an underserved multiplier of 0.22. In other words, they would receive 22 percent of the points from their measure performance scaler because of how the logistic exchange function translates their proportion of residents with DES. Their measure performance scaler of 16 and underserved multiplier of 0.22 would then be multiplied together to get their HEA bonus points of 3.52. Alternatively, example SNF 2 with 14 points and a proportion of residents with DES of 70 percent, received an underserved multiplier of 0.78. Their measure performance scaler of 14 and underserved multiplier of 0.78 would then be multiplied together to get their HEA bonus points of 10.92. Note that although SNF 1 had a higher measure performance scaler, they received fewer HEA bonus points because they had a lower proportion of residents with DES. Finally, example SNF 3 had a proportion of SNF residents with DES of less than 20 percent and so they received an underserved multiplier of 0, resulting in no HEA bonus points

HEA bonus points = Measure Performance Scaler × Underserved Multiplier

TABLE 20—EXAMPLE OF THE HEA BONUS POINTS CALCULATION

Example SNF	Measure performance scaler	Proportion of Residents with DES (%)	Underserved multiplier	HEA bonus points
	[A]	[B]	[C]	[D] ([A]*[C])
SNF 1	16	50	0.22	3.52
SNF 2	14	70	0.78	10.92
SNF 3	10	10	0	0
SNF 4	2	80	0.92	1.84

Step Four—Add HEA Bonus Points to the Normalized Sum of all Points Awarded for each Measure

Finally, we proposed that we will add a SNF's HEA bonus points as calculated in Step Three of this section to the normalized sum of all points awarded to a SNF across all measures. This resulting sum will be the SNF Performance Score earned by the SNF for the program year, except that we will cap the SNF's Performance Score at 100 points to ensure the HEA creates a balanced incentive that has the potential to increase the SNF Performance Score without dominating the score and creating unintended incentives. Table 21 displays the final HEA bonus points added to the normalized sum of all points awarded to a SNF for each measure for 4 example SNFs.

TABLE 21—EXAMPLE OF THE HEA BONUS POINTS CALCULATION

Example SNF	Normalized sum of all points awarded for each measure	HEA bonus points (Step 3, column [D])	SNF performance score
	[A]	[B]	([A] + [B])
SNF 1	80	3.52	83.52
SNF 2	65	10.92	75.92
SNF 3	42	0	42.00
SNF 4	10	1.84	11.84

By adding these HEA bonus points to the normalized sum of all points awarded to a SNF for each measure, SNFs can be rewarded for delivering excellent care to all residents they serve and can be appropriately recognized for the resource intensity expended to achieve high performance when caring for higher proportion of SNF residents with DES. We believe this scoring adjustment, designed to advance health equity through the SNF VBP Program, is consistent with CMS's goal to incentivize greater inclusion of underserved populations, as well as the delivery of high-quality care to all.

We proposed the scoring change and calculations including the use of the measure performance scaler, underserved multiplier, and HEA bonus points. We also proposed to codify this proposal by adding a new paragraph (k) at § 413.338 of our regulations and by updating § 413.338(e) of our regulations to incorporate the health equity scoring adjustment into our performance scoring methodology. We solicited public comment on the HEA.

We received public comments on the HEA proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our HEA noting that it appropriately recognizes the additional challenges and increased resource utilization in meeting the healthcare needs of the underserved population while also rewarding high quality performance for all residents.

Response: We agree that this adjustment recognizes the resource intensity required to care for residents with DES while also supporting high quality care for all residents.

Comment: A few commenters supported the HEA and also suggested next steps for CMS. One commenter encouraged CMS to adequately fund State Medicaid programs. One commenter urged CMS to increase scrutiny on how SNFs that are eligible for the HEA spend their Medicare and Medicaid funds. Another commenter recommended that CMS monitor the HEA for unintended consequences. One commenter suggested that CMS consider whether adjustments to the scoring methodology are necessary to account for an organization's performance specifically within the DES population if it differs from the performance in the rest of the patient population. One commenter requested that CMS consider how the HEA compares to a peer grouping approach.

Response: We intend to closely monitor the data for potential unintended consequences that could arise as a result of the HEA. We agree that it is also important to consider an organization's performance specifically within the DES population, although that is not what this HEA is intended to do. As we explained in the proposed rule (88 FR 21392), we have concerns with utilizing a peer grouping approach because it may set different standards of care. We will take these suggestions into consideration as we develop additional ways to incorporate health equity into the Program.

Comment: A few commenters supported adjusting the SNF VBP Program for health equity but expressed concerns about the details of the proposed HEA. One commenter believed the scoring methodology was too complex and stated that complexity in measures makes changes at the facility level more challenging. One commenter was concerned that high performing facilities with high proportions of residents with DES will get payment adjustments and lower performing facilities with high proportions of residents with DES will not get payment adjustments. The same commenter requested that CMS explore how these lower performing facilities might access scoring adjustments. One commenter was concerned that the HEA may reward facilities for their resident population instead of their quality scores. One commenter suggested CMS

use the term ''patient'' instead of ''resident'' to describe the population of SNF short -stay patients with original Medicare-covered stays.

Response: We disagree that the HEA is too complex. We believe that the scoring methodology addresses the challenges of adding a HEA to high performing SNFs that also care for high proportions of residents with DES in a straightforward way. As stated in the proposed rule (88 FR 21382 through 21392), if a SNF, relative to other SNFs, is in the top third of performance for any measure, they are eligible for HEA bonus points. The number of HEA bonus points that a SNF is eligible to receive depends on its proportion of residents with DES. The HEA bonus points are then incorporated into the calculation of the SNF Performance Score, which is used to determine a SNF's payment adjustment. A SNF that provides care for high proportions of residents with DES and performs well on any measure is likely to receive a higher adjustment due to this addition to the program. Resources will be developed to support SNFs in understanding this new adjustment.

We also reiterate that the HEA is intended to reward high quality performance and not solely adjust for resident population, which may leave lower performing facilities with high proportions of residents with DES without a payment adjustment. We do not intend to reward lower quality performance and we believe the proposed HEA incentivizes lower performing facilities to improve their quality scores. We also agree that it is important to measure health equity in other ways, which is why we included in the proposed rule a request for information on additional ways to incorporate health equity into the Program.

We disagree that the adjustment may reward facilities for their resident population instead of their quality scores as we specifically designed the adjustment to first determine whether the provider is high performing and then apply the underserved multiplier. Lastly, we have used the term ''resident'' to refer to both short- and long-stay residents when referencing the HEA because we use this language throughout the entire proposed and final rules for all measures, including both short and long-stay measures.

Comment: A few commenters did not support our proposed HEA. One commenter believed it was premature to add a health equity component into a payment program and also believed that the long stay measures are unrelated to health equity because the DES population is calculated using Medicare Part A claims. The same commenter also believed the HEA does not provide meaningful data to address health equity, and that the HEA doesn't appropriately incentivize SNFs with a low proportion of residents who are in a Medicare Part A stay or SNFs with a large population of residents enrolled in Medicare Advantage. One commenter believed the proposal is discriminatory and does not consider health equity and instead stated that CMS should include social determinants of health as part of the new quality measures.

Response: We believe the HEA is inclusive as all SNFs that meet the proposed floor of 20 percent of residents with DES are eligible to earn HEA bonus points. As we explained in the proposed rule, there is considerable literature linking negative health outcomes to residents with DES specifically in the SNF setting (88 FR 21383). We designed the HEA to reward high quality care for all residents and to recognize the resource intensity required to care for residents with DES, who are more likely to have disabilities or functional impairments, more likely to be medically complex, more likely to have greater social needs, and have a greater risk of negative health outcomes compared to individuals without DES.[413] We disagree that it is premature to add a health equity component into a payment program. We note that the HEA will not be included until the FY 2027 program year, and we believe it is imperative to incentivize high quality care for all residents in the Program without additional delay. Further, as described above, advancing health equity is a key pillar of our strategic vision [414] and we have already been working to advance health equity by designing, implementing, and operationalizing policies and programs aimed at identifying and reducing health disparities.

We also disagree that long stay measures are unrelated to health equity because the DES population is calculated using Medicare Part A claims. The HEA aims to incentivize high quality care under the SNF VBP Program, while recognizing the resource intensity required to care for residents with DES, by providing health equity bonus points to SNFs that perform well on Program measures and have at least 20 percent of residents with DES. SNFs with a higher proportion of residents with DES also have a higher share of residents who are enrolled in Medicaid in their total resident population, which adds to their resource constraints.[415] Many long-stay residents are enrolled in Medicare Part B, which covers certain services provided by nursing facilities. Thus, to accomplish the goals of the HEA, we feel it is appropriate to include all measures in the SNF VBP Program, including long-stay measures when calculating the HEA.

Regarding the data provided by the HEA, we reiterate the intent of the HEA is not to specifically incentivize improvement among residents with DES but rather incentivize high quality care among all residents in the facility and to recognize the additional resources required to care for residents with DES. Current data relating to the Program, available on the Provider Data Catalog website, provide SNFs with information on their quality performance. We believe the HEA is an important first step in adding a health equity component to the Program; however, we also intend to explore additional ways to incorporate health equity into the Program, which we intend to allow commenters to provide feedback on in future rulemaking.

We disagree with concerns that this HEA might not appropriately incentivize SNFs that have large populations of residents enrolled in Medicare Advantage. We believe this HEA has the ability to improve care for all residents in a SNF as SNFs will need to perform in the top third of performance for at least one measure to be eligible to receive the HEA. Further, SNFs that have a low proportion of Medicare Part A beneficiaries will still be able to earn the HEA based on the proportion of those Medicare Part A beneficiaries who have DES and their performance under the Program. However, we will continue to monitor the HEA after implementation.

We will take the commenter's suggestion to include social determinants of health as part of the new quality measures into consideration as we develop additional ways to incorporate health equity into the Program.

We received public comments on our proposal to utilize DES to define the term ''underserved population''. The following is a summary of the comments we received and our responses.

[413] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032.*

[414] CMS Strategic Vision. (2022). *https://www.cms.gov/cms-strategic-plan.*

[415] Rahman, M., Grabowski, D.C., Gozalo, P.L., Thomas, K.S., & Mor, V. (2014). Are Dual Eligibles Admitted to Poorer Quality Skilled Nursing Facilities? *Health Services Research,* 49(3), 798–817. *https://doi.org/10.1111/1475-6773.12142.*

Comment: Many commenters supported using dual eligibility status (DES) to define the underserved population because it is consistently recorded in administrative data, has a strong link to other social drivers of health, and reflects those who face the most significant social needs.

Response: We thank commenters for their support and agree DES is an important indicator of social need because individuals with DES are more likely to have disabilities or functional impairments, more likely to be medically complex, more likely to have greater social needs, and have a greater risk of negative health outcomes compared to individuals without DES.

Comment: Many commenters encouraged CMS generally to explore other options for defining the underserved population in the future as there are many other social risk factors that impact resident outcomes. A few commenters suggested considering the proportion of Medicaid residents in a facility as part of the definition of ''underserved.'' A few commenters suggested CMS encourage collection of race and ethnicity data and adjust based on the racial composition of facilities.

Response: We thank the commenters for these suggestions.

Comment: A few commenters requested CMS consider adding additional indicators to the definition of ''underserved'' before implementing the HEA in order to create multiple ways to recognize the challenges residents and SNFs may face in achieving better outcomes. One commenter requested the Low-Income Subsidy (LIS) be included in the definition, and one commenter suggested both the LIS and Area Deprivation Index (ADI) be included in the definition of ''underserved.''

Response: As we explained in the proposed rule (88 FR 21384 through 21385), we are concerned that including the ADI or residents eligible for the LIS program as part of our definition of ''underserved'' in the HEA is premature until more research is conducted linking these indicators to negative health outcomes specifically in the SNF setting. We intend to consider these and other indicators as we explore additional ways to incorporate health equity into the Program.

Comment: A few commenters expressed concern over using DES alone to define the underserved population because Medicaid eligibility varies by State. One commenter requested that CMS consider how fluctuations in the number of residents with DES within a SNF over time would impact the scoring methodology and whether this indicator would be stable over the time the measures are collected.

Response: As explained in the proposed rule (88 FR 21386), we proposed to define residents with DES, for purposes of this proposal, as the percentage of Medicare SNF residents who are also eligible for Medicaid. We proposed to assign DES for any Medicare beneficiary who was deemed by Medicaid agencies to be eligible to receive Medicaid benefits for any month during the performance period of the 1-year measures. Because of the concern that Medicaid eligibility varies by state, we are clarifying in this final rule that this definition includes beneficiaries with partial DES. Residents with full DES qualify for full Medicare and Medicaid benefits, whereas residents with partial DES qualify fully for Medicare, but only for some Medicaid benefits, as they have higher amounts of assets and income.[416] We believe this expanded definition of dual eligibility is appropriate for SNF VBP as it allows for the inclusion of a larger number of residents who are underserved. In our modeling that includes residents with partial and full DES, we also considered using eligibility for the Medicare Low Income Subsidy to meet the 20 percent threshold, which does not differ by State and may capture different low-income beneficiaries and found only a small increase in SNFs that became eligible to receive the HEA, compared to only using those with partial and full DES. Given this, we believe that using the definition of DES, which includes residents with both partial and full DES, captures a sufficient proportion of low-income Medicare beneficiaries and is sufficiently consistent across States.

As requested by the commenter, we would like to explain further how fluctuations in the number of residents with DES, including both partial and full DES, within a SNF over time would impact the scoring methodology. We proposed to define the underserved multiplier as the number representing the SNF's proportion of residents with DES out of its total resident population in the applicable program year, translated using a logistic exchange function (88 FR 21385 through 21386). We further defined the total resident population as Medicare beneficiaries identified from the SNF's Part A claims during the performance period of the 1-year measures (88 FR 21385 through 21386). In SNF VBP, the program year refers to the year in which a SNF's payment is impacted and has a corresponding baseline and performance period for each measure. Thus, because the calculation of the program year payment adjustment is dependent on both the performance period and baseline period, we would like to clarify that the underserved multiplier is for a SNF, the mathematical result of applying a logistic function to the number of SNF residents who are members of the underserved population out of the SNF's total Medicare population, as identified from the SNF's Part A claims, during the performance period that applies to the 1-year measures for the applicable program year. A single underserved multiplier will be calculated using the performance period of the 1-year measures and will be applied to all measures in the Program. The periods for calculating measure performance and calculating the proportion of residents with DES therefore overlap. This means that a SNF's proportion of residents with DES may change for each SNF VBP program year, and thus the SNF's underserved multiplier may change for each program year, in the same way that the set of residents used to calculate measure scores for each measure changes. For example, as a SNF's proportion of residents with DES increases, if their performance remains in the top third for the same measure or measures, they will likely receive additional HEA bonus points. As a SNF's proportion of residents with DES decreases, even if their performance remains in the top third for the same measure or measures from previous program years, they will likely receive fewer HEA bonus points. The combination of a SNF's proportion of residents with DES and performance on each measure will determine how many HEA bonus points a SNF receives, and both proportion of residents and performance on each measure can change from year to year.

Comment: One commenter did not support using DES until additional research is conducted as they believe utilizing DES to define the underserved population could lead to unintended consequences. Specifically, they believe CMS may unintentionally increase the financial disparity that exists between for-profit and not-for-profit nursing homes by rewarding for-profit nursing homes with higher DES percentages and not rewarding not-for-profit nursing homes that care for higher proportions of Medicaid-only residents.

Response: We disagree that the HEA will necessarily increase the disparity

[416] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

between SNFs that care for higher proportions of residents with DES compared to those with higher proportions of Medicaid-only residents as our definition of DES includes the total resident population, which we further defined as Medicare beneficiaries identified from the SNF's Part A claims (88 FR 21386), as the denominator. Thus, although a SNF may have lower proportions of residents with Medicare overall, the proportion of DES only takes into consideration the proportion of residents with Medicare who also have Medicaid. Additionally, we note that the HEA is intended to recognize and reward all SNFs for providing excellent care to higher proportions of residents with DES.

We also solicited public comments on utilizing a measure performance scaler, assigning a point value of 2 for each measure for which a SNF is a top tier performing SNF, and defining a top tier performing SNF as a SNF whose performance for the program year is in the top third of the performance of all SNFs on the measure for the same program year. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported this proposal to recognize SNFs that perform in the top third.

Response: We agree that recognizing performance in the top third is appropriate because it strikes a balance between rewarding high quality performance and providing an appropriate payment adjustment to those who perform well and serve a high proportion of residents with DES while incentivizing lower performing SNFs to improve.

Comment: A few commenters suggested CMS limit those receiving a bonus to SNFs in the top 20 percent of performance instead of the top third.

Response: We thank the commenters for their recommendation but believe recognizing performance in the top third strikes a balance between rewarding high quality performance and providing an appropriate payment adjustment to those who perform well and serve a high proportion of residents with DES while still incentivizing lower performing SNFs to improve. Further, as explained in the proposed rule (88 FR 21385) based on our calculation of measure data from FY 2018 to 2021, the average SNF Performance Score for SNFs in the top third of performance that care for high proportions of residents with DES (SNFs with proportions of residents with DES in the top third) is 8.4 points lower than the SNF Performance Score for SNFs in the top third of performance that do not care for high proportions of residents with DES (40.8 for high performing SNFs with high proportions of residents with DES and 49.2 for all other high performing SNFs). Because of these existing performance disparities between SNFs that serve a high proportion of residents with DES and those that do not, setting the performance threshold too high may inadvertently exclude SNFs that serve a high proportion of residents with DES from the HEA. In the future, we may consider raising the performance threshold for the HEA based on ongoing monitoring of SNF performance, especially among those in the top tier.

Comment: One commenter expressed concern that if there is low variability in a measure score between the top and bottom third, there may not be a clinically meaningful difference.

Response: Although we recognize that some measures may have low variability in performance, we aim to reward high performing SNFs and incentivize lower performing SNFs to improve, even if those are small improvements. We believe setting the high-performance threshold at the top third strikes this balance regardless of variability in the measure.

Comment: A few commenters expressed their support for assigning a point value of 2 for each measure and noted their interest in commenting on future rulemaking if this changes as the program expands.

Response: We thank the commenters for their support. We agree that assigning a point value of 2 is appropriate at this time and would use rulemaking to propose any revisions to this policy.

We also solicited public comments on using an underserved multiplier to calculate the HEA, utilizing a logistic exchange function to calculate the underserved multiplier, and setting a floor of 20 percent for a SNF to be eligible for any HEA bonus points. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the use of a logistic exchange function to calculate the underserved multiplier.

Response: We thank the commenter for their support.

Comment: A few commenters supported the proposal that a SNF's population must include at least 20 percent of residents with DES in order to be eligible for the underserved multiplier especially since those who do not meet this floor will not be penalized.

Response: We thank commenters for their support of the 20 percent floor.

Comment: One commenter expressed concerns about the 20 percent floor noting that they would prefer for there to be no floor.

Response: We disagree that it would be preferable to not have a 20 percent floor. As noted in the proposed rule (88 FR 21388), we strongly believe a floor of 20 percent allows us to accomplish our goals of this adjustment. Specifically, the 20 percent floor reinforces that the adjustment is intended to appropriately measure performance by rewarding SNFs that are serving higher proportions of SNF residents with DES while also achieving high performance. We believe this approach is necessary to remain consistent with the goal to reward high quality care specifically among SNFs that care for higher proportions of SNF residents with DES. We anticipate the vast majority of SNFs will be able to earn HEA bonus points despite this floor. We also believe that the challenges associated with caring for residents with DES, a complex resident population, would be negligible if greater than 80 percent of a SNF's resident population is not underserved because residents with DES are more likely to have disabilities or functional impairments, more likely to be medically complex, more likely to have greater social needs, and have a greater risk of negative health outcomes compared to those without DES.[417]

After consideration of public comments, we are finalizing the Health Equity Adjustment for the SNF VBP Program beginning with the FY 2027 program year.

We are also finalizing our definition of ''underserved multiplier'' as the mathematical result of applying a logistic function to the number of SNF residents who are members of the underserved population out of the SNF's total Medicare population, as identified from the SNF's Part A claims, during the performance period that applies to the 1-year measures for the applicable program year. We are also finalizing our definition of ''underserved population'' as Medicare beneficiaries who are SNF residents in a Medicare Part A stay who are also dually eligible, both partial and full, for Medicaid.

Further, in an effort to minimize burden on providers, we aim to align our Health Equity Adjustment to a

[417] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope),* 38(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032.*

similar adjustment proposed for inclusion in the Hospital Value Based Purchasing Program as is feasible and appropriate. As part of this alignment, we are making a technical change to our definition of the health equity adjustment bonus points so the definition is as follows: the points that a SNF can earn for a program year based on its performance and proportion of SNF residents who are members of the underserved population.

We are also finalizing the updates to our regulations at § 413.338 to reflect this Health Equity Adjustment, including the clarified definitions of the ''underserved multiplier,'' ''underserved population,'' and ''health equity adjustment bonus points.''

e. Increasing the Payback Percentage To Support the HEA

We previously adopted 60 percent as the SNF VBP Program's payback percentage for FY 2019 and subsequent fiscal years, subject to increases as needed to implement the Program's Low-Volume Adjustment policy for SNFs without sufficient data on which to base measure scores. We based this decision on numerous considerations, including our estimates of the number of SNFs that receive a positive payment adjustment under the Program, the marginal incentives for all SNFs to reduce hospital readmissions and make quality improvements, and the Medicare Program's long-term sustainability. We also stated that we intended to monitor the effects of the payback percentage policy on Medicare beneficiaries, on participating SNFs, and on their measured performance, and we stated that we intended to consider any adjustments to the payback percentage in future rulemaking.

In previous rules, we have received many public comments urging us to increase the payback percentage. For example, in the FY 2018 SNF PPS final rule (82 FR 36620), we responded to comments urging us to finalize a 70 percent payback percentage. We stated at that time that we did not believe that a 70 percent payback percentage appropriately balanced the policies that we considered when we proposed the 60 percent policy. We responded to similar comments in the FY 2019 SNF PPS final rule (83 FR 39281), where commenters urged us to revisit the payback percentage policy and adopt 70 percent as the Program's policy. We reiterated that we did not believe it was appropriate to revisit the payback percentage at that time, which was prior to the Program's first incentive payments taking effect on October 1, 2018.

As part of our ongoing monitoring and evaluation efforts associated with the SNF VBP Program, we considered whether to update the Program's payback percentage policy to support the proposed HEA. After our consideration, and in conjunction with the HEA bonus points, we proposed to increase the total amount available for a fiscal year to fund the value-based incentive payment amounts beginning with the FY 2027 program year.

We proposed this update to our payback percentage policy both to increase SNFs' incentives under the Program to undertake quality improvement efforts and to minimize the impact of the proposed HEA on the distribution of value-based incentive payments to SNFs that do not earn the HEA. Because the SNF VBP Program's value-based incentive payment amounts depend on the distribution of SNF Performance Scores in each SNF VBP program year, providing additional incentives to SNFs serving higher proportions of SNF residents with DES without increasing the payback percentage could reduce other SNFs' value-based incentive payment amounts. While we do not believe that those reductions would be significant, we view that a change to the payback percentage will further increase SNFs' incentivizes to implement effective quality improvement programs.

In determining how to modify the payback percentage, we considered the maximum number of HEA bonus points that would be awarded, as it is important that those points translate into meaningful enough rewards for SNFs to meet our goals of this adjustment to appropriately measure performance by rewarding SNFs that overcome the challenges of caring for higher proportions of SNF residents with DES and to incentivize SNFs who have not achieved such high-quality care to work towards improvement. However, we also have to ensure that the additional HEA bonus points available do not lead to value-based incentive payments that exceed the maximum 70 percent payback percentage authorized under section 1888(h)(5)(C)(ii)(III) of the Act. Additionally, we considered the maximum number of HEA bonus points that would be awarded in comparison to the average SNF Performance Score as we believe providing more HEA bonus points for the HEA relative to the average a SNF receives for their performance on the Program measures could undermine the incentives for SNFs to perform in the SNF VBP Program.

We conducted an analysis utilizing FY 2018 through FY 2021 measure data for our previously finalized and new measures, including a simulation of performance from all 8 measures for the FY 2027 Program, to determine what would be the greatest amount we could increase the payback percentage by for the HEA while not exceeding the 70 percent maximum or allowing for too many HEA bonus points. We examined the interaction of the two factors that directly impact the size of the incentives, the assigned point value for each measure and the payback percentage. For the first factor, as stated previously, we proposed to assign 2 points per measure to each SNF that is a top tier performing SNF for that measure. This assigned point value would be used to calculate the measure performance scaler and resulting HEA bonus points. In this analysis, we also tested alternatives of assigning a point value of 1 or 3 per measure to determine how each option would impact the payback percentage and resulting value-based incentive payment amounts. For the payback percentage factor, we tested increasing the payback percentage to a fixed amount of 65 percent. We also tested an option in which we allow the payback percentage to vary based on performance data such that SNFs that do receive the HEA would not experience a decrease in their value-based incentive payment amount, to the greatest extent possible, relative to no HEA in the Program and maintaining a payback percentage of 60 percent.

Table 22 has three columns representing possible point values assigned to each measure that are then used to calculate the measure performance scaler. As shown in Table 22, regardless of the assigned points per measure, 78 percent of SNFs would receive the HEA in this analysis. This means that 78 percent of SNFs were top tier performing SNFs for at least 1 measure and had at least 20 percent of their residents with DES, and therefore would have received some HEA bonus points. Table 22 also shows the mean number of HEA bonus points per SNF receiving the HEA, as well as the HEA bonus points at the 90th percentile and the maximum HEA bonus points that would have been received for the HEA. Table 22 then provides an estimate of the payback percentage that would have been required such that SNFs that do receive the HEA would not experience a decrease in their value-based incentive payment amount, to the greatest extent possible, relative to no HEA in the Program and maintaining a payback percentage of 60 percent. This analysis

also identified that the average SNF, prior to the implementation of the HEA, would have received a SNF Performance Score of 31.6 and that the 90th percentile SNF Performance Score was 49.7.

As stated previously, we proposed to assign a point value of 2 for each measure in which a SNF is a top tier performing SNF. Table 22 shows that assigning a point value of 2 per measure would have resulted in a 66 percent payback percentage, meaning once all SNFs have been awarded HEA bonus points, the value-based incentive payment amounts would result in a payback percentage of 66 percent. Assigning a point value of any higher number, such as 3 points per measure could result in the payback percentage exceeding the 70 percent maximum. This is because the amount of HEA bonus points would vary with performance, and so we expect the HEA bonus points to vary from year to year, creating a significant risk that assigning a point value of 3 for each measure would result in a payback percentage above the 70 percent maximum. Further, assigning a point value of 3 for each measure would result in HEA bonus points as high as 20. Considering the average SNF Performance Score during this same time period would have been 31.6, the addition of 20 bonus points puts far too much weight on the HEA compared to each of the Program measures.

TABLE 22—ESTIMATED HEA BONUS POINTS AND PAYMENT ADJUSTMENTS RESULTING FROM SCORING OPTIONS BASED ON FY 2018–2021 DATA

	1 assigned point value per measure	2 assigned point value per measure	3 assigned point value per measure
SNFs receiving HEA			
Total Number of SNFs receiving HEA	10,668	10,668	10,668
Percentage of SNFs receiving HEA	78%	78%	78%
HEA bonus points (among SNFs receiving HEA)			
Mean	0.89	1.78	2.68
90th percentile	2.25	4.50	6.76
Max	6.67	13.33	20.00
Assume payback will vary based on assigned points per measure			
Estimate of percent payback required such that SNFs not receiving the HEA would not experience a decrease in their value-based incentive payment amount*	63%	66%	69%
Amount to SNFs receiving HEA ($MM)	$14.3	$29.6	$45.3

Notes:
* Relative to no HEA in the Program and maintaining a payback percentage of 60 percent.

Because we proposed to assign a point value of 2 for each measure in the Program and based on this analysis, we proposed that the payback percentage would vary by program year to account for the application of the HEA such that SNFs that do receive the HEA would not experience a decrease in their value-based incentive payment amount, to the greatest extent possible, relative to no HEA in the Program and maintaining a payback percentage of 60 percent. Utilizing a variable approach ensures a very limited number of SNFs (if any) that do not receive HEA bonus points will experience a downward payment adjustment. For a given program year, we proposed to calculate the final payback percentage using the following steps. First, we will calculate SNF value-based incentive payment amounts with a payback percentage of 60 percent and without the application of the proposed HEA. Second, we will identify which SNFs receive the HEA, and which do not based on their proportion of residents with DES and individual measure performance. Third, while maintaining the value-based incentive payment amounts calculated in the first step for those SNFs that do not receive the HEA, we will calculate the payback percentage needed to apply the HEA as described in section VIII.E.4.d. of this final rule. As shown in Table 23, through our analysis, we estimated that assigning 2 points per measure would require an increase in the 60 percent payback percentage of 6.02 percentage points for the FY 2027 program year and 5.40 percentage points for the FY 2028 program year. These are estimates and we would expect some variation that could be the result of SNFs with high proportions of residents with DES significantly changing their performance, changes in Medicaid eligibility requirements such that the proportions of residents with DES changes, changes to the Program such as adding additional measures which could add additional points available for the HEA, and other possible factors. For the last factor, increasing the points available could result in an increased payback percentage beyond the 70 percent maximum; however, we intend to adjust the number of points available through the rulemaking process if we add measures to the Program. With our current proposal of assigning a point value of 2 for each measure, we do not anticipate that any factors will result in an increase in payback beyond the 70 percent maximum. However, we will continue to monitor the data closely and intend to make further proposals if necessary, in future rulemaking. Thus, as shown in Table 23, a variable payback percentage will allow all SNFs that receive the HEA to also receive increased value-based incentive payment amounts, and also means that SNFs that do not receive the HEA will not experience a decrease in their value-based incentive payment amount, to the greatest extent possible, relative to no HEA in the Program and maintaining a payback percentage of 60 percent.

We also explored setting a fixed payback percentage of 65 percent. This would mean that despite assigning higher point values for each measure, the resulting value-based incentive payment amounts would be capped to ensure the payback percentage would not exceed 65 percent. This would ensure that the payback percentage is below the 70 percent maximum. However, as shown in Table 23,

including a fixed percentage point payback would result in some SNFs, including SNFs that care for the highest quintile of residents with DES and almost one-third of rural SNFs, receiving reduced value-based incentive payment amounts compared to the absence of the HEA in the Program. This would be a significant negative consequence of this proposal, and our proposal is structured to avoid this outcome. We do not want SNFs that provide high quality care and that serve large proportions of residents who are underserved to be disadvantaged by this HEA.

TABLE 23—ESTIMATED DIFFERENCES FOR THE FY 2027 AND 2028 PROGRAM YEARS BETWEEN A VARIABLE PAYBACK PERCENTAGE AND A FIXED PAYBACK PERCENTAGE BASED ON FY 2018–2021 DATA *

	FY 2027 program		FY 2028 program	
	Variable **	Fixed	Variable **	Fixed
Payback percentage	66.02%	65%	65.40%	65%
# (%) SNFs worse off *** among . . .				
All SNFs	0 (0%)	5,233 (38%)	0 (0%)	4,105 (29%)
Rural SNFs	0 (0%)	1,146 (32%)	0 (0%)	853 (23%)
SNFs in the highest quintile of proportion of their residents with DES	0 (0%)	372 (14%)	0 (0%)	409 (15%)
Mean value-based incentive payment amount change per SNF among . . .				
All SNFs	$2,162	$1,796	$1,901	$1,759
SNFs that are worse off ***	$0	($366)	$0	($162)
SNFs that are better off ***	$2,771	$3,136	$2,433	$2,552
Rural SNFs	$969	$808	$940	$877
SNFs in the highest quintile of proportion of their residents with DES	$5,997	$5,691	$4,949	$4,846
Value-based incentive payment amounts				
Amount of value-based incentive payments with HEA ($MM)	$324.18	$319.17	$323.23	$321.24
Amount of value-based incentive payments without HEA (60% of withhold) ($MM)	$294.62	$294.62	$296.53	$296.53
Amount of increase due to HEA ($MM)	$29.56	$24.55	$26.70	$24.71

Notes:
* Based on assigning a point value of 2 for each measure in which the SNF is a top tier performing SNF.
** Actual payback percentage may change from what was modeled based on final Program data.
*** Payment changes, ''worse off'', and ''better off'' all compare to the absence of the HEA in the Program and a payback percentage of 60 percent.

We proposed to adopt a variable payback percentage and proposed to amend our regulations at § 413.338(c)(2)(i) to reflect this change to the payback percentage for FY 2027 and subsequent fiscal years. We solicited public comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to increase the payback percentage. A few of these commenters also urged CMS to pay out the full 70 percent allowable by statute.

Response: We thank commenters for their support. As noted in the FY 2018 rule (82 FR 36619 through 36620), the 60 percent payback percentage was set to appropriately balance the number of SNFs that receive a positive payment adjustment, the marginal incentives for all SNFs to reduce hospital readmissions and make broad-based care quality improvements, and the Medicare Program's long-term sustainability through the additional estimated Medicare trust fund savings. We continue to hold those goals for the payback percentage as we have expanded the Program. We believe it is appropriate to utilize the additional payback to specifically target the HEA, but we continue to balance each of the considerations listed above and do not believe it is appropriate to increase the payback percentage beyond what will be used to fund the HEA at this time.

Comment: A few commenters supported the use of a variable payback percentage as long as it stays under the 70 percent threshold allowable by statute.

Response: We thank the commenters for their support of the variable payback percentage and agree that we do not intend to allow the payback percentage to increase beyond the 70 percent threshold. We reiterate we will continue to monitor the data closely and intend to make further proposals if necessary, in future rulemaking.

After consideration of public comments, we are finalizing the updates to the payback percentage and codifying those updates in our regulations.

5. Health Equity Approaches Under Consideration for Future Program Years: Request for Information (RFI)

We are committed to achieving equity in health outcomes for residents by promoting SNF accountability for health disparities, supporting SNFs' quality improvement activities to reduce these disparities, and incentivizing better care for all residents. The Health Equity Adjustment, as described previously, will revise the SNF VBP scoring methodology to reward SNFs that provide high quality care to residents with DES and create an incentive for all SNFs to treat residents with DES. We also aim to incentivize the achievement of health equity in the SNF VBP Program in other ways, including focusing specifically on reducing disparities to ensure we are incentivizing improving care for all populations, including residents who may be underserved. In order to do so, we solicited public comment on possible health equity advancement approaches to incorporate into the Program in future program years that could supplement the Health Equity Adjustment described in section VIII.E.4 of this final rule. We are also seeking input on potential ways to assess improvements in health equity in SNFs.

As is the case across healthcare settings, significant disparities persist in the skilled nursing environment.[418] [419] [420] [421] The goal of explicitly incorporating health equity-focused components into the Program is to both measure and incentivize equitable care in SNFs. By doing so, we not only aim to encourage SNFs to focus on achieving equity for all residents, but also to afford individuals and families the opportunity to make more informed decisions about their healthcare.

The RFI consists of four main sections. The first section requested input on resident-level demographic and social risk indicators, as well as geographic-level indices that could be used to assess health equity gaps. The second section requested input on possible health equity advancement approaches that could be added to the Program and describes questions that should be considered for each. The third section requested input on other approaches that could be considered for inclusion in the SNF VBP Program in conjunction with the approaches described in the second section. Finally, the fourth section requested input on adopting domains that could incorporate health equity.

a. Resident-Level Indicators and Geographic-Level Indices To Assess Disparities in Healthcare Quality

To identify SNFs that care for residents who are underserved and determine their performance among these populations, we need to select an appropriate indicator of such. Identifying and prioritizing social risk or demographic variables to consider for measuring equity can be challenging. This is due to the high number of variables that have been identified in the literature as risk factors for poorer health outcomes and the limited availability or quality of standardized data. Each source of data has advantages and disadvantages in identifying populations to assess the presence of underlying disparities. Income-based indicators are a frequently used measure for assessing disparities,[422] but other social risk indicators can also provide important insights. As described in section VIII.E.4. of this final rule, we proposed to utilize dual eligibility status (DES) to measure the underserved population in SNFs, as this data is readily available and DES as a metric has been used extensively to study the SNF population.[423] [424] However, as additional data and research becomes available, we may be able to utilize other social risk factors to define the underserved population. We refer readers to the ASPE Report to Congress on Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs for additional indicators we could consider for use in the Program, including the LIS Program, ADI, and others.[425] We solicited comment on which demographic variables, social risk indicators, or combination of indicators would be most appropriate for assessing disparities and measuring improvements in health equity in the SNF VBP Program for the health equity approaches described in this RFI. We provide a summary of the comments we received, and our responses, later in this section.

b. Approaches To Assessing Health Equity Advancement in the SNF VBP Program

We are interested in developing approaches that would incentivize the advancement of health equity for all SNFs, focusing on improving care for all residents, including those who may currently face disparities in their care. Such an approach would aim to include as many SNFs as possible and would not be restricted to those serving 20 percent or more of residents with DES like the Health Equity Adjustment we discuss in section VIII.E.4. of this final rule. There are many different ways to add a health equity-focused component or adjustment to the Program to meet these objectives. In the FY 2023 SNF PPS proposed rule (87 FR 22789), we requested commenters' views on which adjustments would be most effective for the SNF VBP Program to account for any equity gaps that we may observe in the SNF setting. Although many commenters were supportive of incorporating health equity-focused adjustments into the Program, there was no clear consensus on the type of adjustment that would be most effective. Therefore, we requested additional comments on potential approaches to assessing health equity advancement in the Program. We have outlined approaches to assess underlying equity gaps or designed to promote health equity, which may be considered for use in the Program and grouped them into three broad categories for assessment: applying points to current measures, equity-focused measures, and composite measures. The remainder of this section discusses these categories and relevant questions to consider for each. We also highlight two methods used for calculating disparities.

We identified four key considerations that we should consider when employing quality measurement as a tool to address health disparities and advance health equity. When considering which equity-focused measures could be prioritized for development for SNF VBP, we examined past reports that assess such measures and encouraged commenters to review each category against the following considerations: [426] [427]

[418] Li, Y., Glance, L.G., Yin, J., & Mukamel, D.B. (2011). Racial Disparities in Rehospitalization Among Medicare Patients in Skilled Nursing Facilities. *American Journal of Public Health, 101*(5), 875–882. *https://doi.org/10.2105/AJPH.2010.300055.*

[419] Rahman, M., Grabowski, D.C., Gozalo, P.L., Thomas, K.S., & Mor, V. (2014). Are Dual Eligibles Admitted to Poorer Quality Skilled Nursing Facilities? *Health Services Research, 49*(3), 798–817. *https://doi.org/10.1111/1475-6773.12142.*

[420] Rivera-Hernandez, M., Rahman, M., Mukamel, D., Mor, V., & Trivedi, A. (2019). Quality of Post-Acute Care in Skilled Nursing Facilities That Disproportionately Serve Black and Hispanic Patients. *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences, 74*(5). *https://doi.org/10.1093/gerona/gly089.*

[421] Zuckerman, R.B., Wu, S., Chen, L.M., Joynt Maddox, K.E., Sheingold, S.H., & Epstein, A.M. (2019). The Five-Star Skilled Nursing Facility Rating System and Care of Disadvantaged Populations. *Journal of the American Geriatrics Society, 67*(1), 108–114. *https://doi.org/10.1111/jgs.15629.*

[422] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[423] Rahman, M., Grabowski, D.C., Gozalo, P.L., Thomas, K.S., & Mor, V. (2014). Are Dual Eligibles Admitted to Poorer Quality Skilled Nursing Facilities? *Health Services Research,* 49(3), 798–817. *https://doi.org/10.1111/1475-6773.12142.*

[424] Zuckerman, R.B., Wu, S., Chen, L.M., Joynt Maddox, K.E., Sheingold, S.H., & Epstein, A.M. (2019). The Five-Star Skilled Nursing Facility Rating System and Care of Disadvantaged Populations. *Journal of the American Geriatrics Society,* 67(1), 108–114. *https://doi.org/10.1111/jgs.15629.*

[425] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

[426] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[427] RAND Health Care. 2021. Developing Health Equity Measures. Washington, DC: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, and RAND Health Care.

• *To what extent does the approach support consumer choice?* It is essential that quality measures reflect consumer needs and allow consumers to make informed choices about their care.[428] [429] In the Program, measure data is available on the Provider Data Catalog website. Having access to and understanding this data would empower consumers with more information in selecting their optimal SNF, including one that demonstrates greater performance in advancing equity.

• *How long would it take to include this approach in the program?* Some approaches may take considerably longer than others to include in the Program. For instance, we intend to consult the consensus-based entity for any new measures we proposed to ensure to have appropriate feedback, which would add additional time to their development. Although we do not want this time to deter interested parties from recommending measures for inclusion in the program, we are interested in understanding commenters' prioritization of measures as it relates to the amount of time they may take to implement when deciding on the best approach for the Program.

• *Is this approach aligned with other Medicare quality reporting and VBP programs?* Implementing quality initiatives requires time and resources.[430] It is one of our top priorities to ensure alignment between quality programs to limit the burden of quality reporting and implementation. Thus, it is important for us to consider when developing a health equity component, if and how other programs are incorporating health equity to align and standardize measures wherever possible.

• *What is the impact on populations that are underserved or the SNFs that serve these populations?* Although the goal of a health equity-focused adjustment to the Program would be to decrease disparities and incentivize high-quality care for all populations including those who are underserved, we also want to create appropriate guardrails that protect SNFs against potential unintended consequences. It is important for us to understand if any proposed approach may create potential negative consequences for residents who are underserved or the SNFs that treat these individuals and any steps we can take to mitigate that.

(1) Applying Points to Current Measures To Assess Health Equity

The first category of health equity advancement approaches we requested comments on are mechanisms that apply points to current measures to assess health equity, rewarding SNFs based on the extent to which they provide equitable care. This category affords each SNF the ability to score additional points for all measures where they demonstrate a high level of equity or a reduction in disparities over time. An approach that applies points to current measures to assess health equity could include, but is not limited to, the following:

• Points applied to one, some, or all measures for SNFs that achieve higher health equity performance on those measures. This would include measuring a SNF's performance on each measure for residents who are undeserved and comparing that to the same SNF's performance among all other residents on the same measures effectively assessing health equity gaps. This approach would utilize a Within-Facility Disparity method for assessing disparities, as described in more detail later in this section.

• Points applied to one, some, or all measures for SNFs that have better performance among residents who are underserved. This would include only measuring performance among residents who are underserved and comparing that performance across all SNFs. This approach would utilize an Across-Facility Disparity method for assessing disparities, as described in more detail later in this section.

• Points applied to one, some, or all measures based on a weighted average of each SNF's performance among resident groups with the worst and best outcomes for each measure. We could define resident groups by any social risk indicator, for example DES. This approach measures performance among all residents in the SNF and places greater weight on the performance of the worst performing group, with the goal of raising the quality floor at every SNF.

We note that any social risk indicator could be used to assess health equity gaps. We welcomed comments on any approach outlined in this section or any other approach that applies additional points to current measures to assess health equity that should be considered for inclusion in the SNF VBP Program.

(2) New Measure Approach

The second category of health equity advancement approaches we requested comments on is a new health equity-focused measure, which would be included as one of the 10 allowable measures in the Program. This category includes the development of a new measure that assesses health equity and could include a structural, process, or outcome measure. A health equity-focused measure would be included as one of the measures in the program and thus would be included in the scoring calculations like other measures. A health equity-focused measure could include, but is not limited to, the following:

• A structural measure. For example, a facility commitment to health equity measure, in which SNFs are assessed on factors like leadership engagement, data collection, and improvement activities that support addressing disparities in quality outcomes. This measure could be similar to the ''Hospital Commitment to Health Equity'' measure that was finalized in the FY 2023 Inpatient Prospective Payment System/Long Term Care Hospital Prospective Payment System final rule (87 FR 48785).

• A process measure. For example, a drivers of health measure, in which residents are screened for specific health-related social needs (HRSNs) to ensure a successful transition home, like transportation or food insecurity. This measure could be similar to the ''Screening for Social Drivers of Health'' measure that was finalized in the FY 2023 Inpatient Prospective Payment System/Long Term Care Hospital Prospective Payment System final rule (87 FR 48785).

• An outcome measure. For example, a measure that is calculated using data stratified for specific populations that are underserved, such as residents with DES.

We note that each of these possible measures are only suggestions for what might be included in the Program. We welcomed comments on any measures that should be considered for inclusion in the SNF VBP Program including the ones described in this section and what data sources should be considered to construct those measures.

(3) Composite Measure Approach

The third category of health equity advancement approaches we requested comments on is the development and

[428] Heenan, M.A., Randall, G.E., & Evans, J.M. (2022). Selecting Performance Indicators and Targets in Health Care: An International Scoping Review and Standardized Process Framework. *Risk Management and Healthcare Policy, 15,* 747–764. *https://doi.org/10.2147/RMHP.S357561.*

[429] Meyer, G.S., Nelson, E.C., Pryor, D.B., James, B., Swensen, S.J., Kaplan, G.S., Weissberg, J.I., Bisognano, M., Yates, G.R., & Hunt, G.C. (2012). More quality measures versus measuring what matters: A call for balance and parsimony. *BMJ Quality & Safety, 21*(11), 964–968. *https://doi.org/10.1136/bmjqs-2012-001081.*

[430] Blanchfield, B.B., Demehin, A.A., Cummings, C.T., Ferris, T.G., & Meyer, G.S. (2018). The Cost of Quality: An Academic Health Center's Annual Costs for Its Quality and Patient Safety Infrastructure. *Joint Commission Journal on Quality and Patient Safety, 44*(10), 583–589. *https://doi.org/10.1016/j.jcjq.2018.03.012.*

implementation of a new health equity-focused composite measure. An equity-focused composite measure would be included as one of the 10 allowable measures in the program and thus would be included in the scoring calculations like other measures. Generally, a composite measure can provide a simplified view of a rather complex topic by combining multiple factors into one measure. A composite measure could include, but is not limited to, the following:

- A composite of all measure scores for residents who are underserved to compare across all SNFs. This could utilize an Across-Facility Disparity method for assessing disparities, as described in more detail later in this section.
- A composite of the health disparity performance within each SNF for some or all measures. This approach could utilize a Within-Facility Disparity method for assessing disparities, as described in more detail later in this section.

We noted that any social risk indicator could be used to assess health equity gaps. We welcomed comments on each of the composite measures described in this section. We also welcomed comments on the specific factors or measures that should be included in a composite measure.

In considering whether to include in the Program any of the approaches described in this section, points applied to current measures based on equity, new measures, or composite measures, we encouraged commenters to consider the following questions:

- *To what extent do these approaches support consumer choice?* What approaches described in this section best support consumer choice? Would any approach be easier to interpret than others? Would any of the approaches described in this section provide information that other approaches would not that would aid consumer choice? Are there other factors we should consider in developing any of the approaches described in this section that are easiest for consumers to utilize and understand? How should any of the approaches described in this section be displayed and shared with consumers to facilitate understanding of how to interpret the approach?
- *How long would it take to include this approach in the program?* If some approaches would take longer to implement, should they still be considered for inclusion in the Program or should a different approach be prioritized? For instance, a measure that is already being utilized by another program could be implemented sooner than a measure that still needs to be developed. Should any of the approaches described in this section be considered regardless of the time it would take to include the approach in the Program?
- *Is this approach aligned with other Medicare quality reporting and VBP programs?* Are there similar approaches to those described in this section that are aligned with other programs that we should consider for SNF VBP? If any of the approaches described in this section are not aligned with other programs, should they still be considered for inclusion in the Program? If these approaches are only aligned somewhat with other programs, should they still be considered for inclusion in the Program? Several other programs, including the End-Stage Renal Disease Quality Incentive Program, the Merit-based Incentive Payment System, the Hospital Inpatient Quality Reporting Program, the Inpatient Psychiatric Facility Quality Reporting Program, and the PPS-Exempt Cancer Hospital Quality Reporting Program also submitted equity-focused measures to the 2022 MUC List that could be considered for the Program.[431] Further, we are in the process of developing a Hospital Equity Index. Should any of these measures be considered for SNF VBP?
- *What is the impact on populations that are underserved or the SNFs that serve these populations?* Are there any potential impacts, including negative or positive unintended consequences, that could occur when implementing the approaches described in this section? Are there steps we should take to mitigate any potential negative unintended consequences? How can we ensure these approaches provide a strong enough incentive to improve care for all populations by identifying areas of inequities? We are interested in all perspectives and particularly of those living in and serving underserved communities.

(4) Disparity Method Approaches

Many of the approaches described previously in this section would rely on calculating disparities. There are several different conceptual approaches to calculating disparities to assess health equity gaps. Currently in the acute care setting, two complementary approaches are used to confidentially provide disparity information to hospitals for a subset of existing measures. The first approach, referred to as the Within-Facility Disparity method, compares measure performance results for a single measure between subgroups of patients with and without a given factor. This type of comparison directly estimates disparities in outcomes between subgroups and can be helpful to identify potential disparities in care. This type of approach can be used with most measures that include patient-level data. The second approach, referred to as the Across-Facility Disparity method, provides performance on measures for only the subgroup of patients with a particular social risk factor. These approaches can be used by a SNF to compare their own measure performance on a particular subgroup of patients against subgroup-specific State and national benchmarks. Alone, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance, these approaches may provide detailed information about where differences in care may exist or where additional scrutiny may be appropriate. For example, the Across-Facility Disparity method indicates that a SNF underperformed (when compared to other SNFs on average) for patients with a given social risk indicator, which would signal the need to improve care for this population. However, if the SNF also underperformed for patients without that social risk indicator (the Within-Facility Disparity method, as described earlier in this section), the measured difference, or disparity in care, could be negligible even though performance for the group that particular social risk factor remains poor. We refer readers to the technical report describing the CMS Disparity Methods in detail, as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the posted Disparity Methods Updates and Specifications Report posted on the QualityNet website at *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

We solicited comments on all of the approaches to assessing health equity advancement described above, as well as whether similar approaches to the two discussed in the previous paragraph could be used for calculating disparities to assess health equity in a SNF. These calculations would then be used for scoring purposes for each of the approaches described previously in this section, either to calculate a SNF's performance on a new measure or a composite measure, or to determine the amount of points that should be applied to current measures to assess heath

[431] *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

equity. We provide a summary of the comments we received, and our responses, later in this section.

c. Other Approaches To Assessing Health Equity Advancement in the SNF VBP Program

There are also many other health equity approaches that could be considered for inclusion in the Program. In particular, we explored risk adjustment, stratification/peer grouping, and adding improvement points when developing the Health Equity Adjustment discussed in section VIII.E.4. of this final rule. We have specific concerns when applying each of those approaches to the SNF VBP Program independently; however, we solicited comment on the potential of incorporating these approaches. We provide a summary of the comments we received, and our responses, later in this section.

d. Development of Domains and Domain Weighting for Inclusion in the SNF VBP Program

As we expand the number of measures on which we assess performance under the SNF VBP Program, we are considering whether we should group the measures into measure domains. Creating domains would align the SNF VBP Program with other CMS programs such as the Hospital Value-Based Purchasing (VBP) Program. The Hospital VBP Program currently groups its measures into four domains that are defined based on measure type, and then weights the sum of a hospital's performance score on each measure in the domain such that the domain is weighted at 25 percent of the hospital's total performance score. Although the Hospital VBP Program uses four domains, each with a 25 percent weight, we could consider for the SNF VBP Program, grouping measures into a different number of domains and then weighting each domain by different amounts.

We solicited comments on whether we should consider proposing the addition of quality domains for future program years. We also solicited comments on if those domains should be utilized to advance health equity in the Program.

The following is a summary of all the comments we received on this health equity RFI including resident-level indicators and geographic-level indices to assess disparities in healthcare quality, approaches to assessing health equity, other approaches to assessing health equity, and the development of domains and domain weighting.

Comment: A few commenters supported CMS implementing policies in the SNF VBP Program to address health equity. One commenter recommended that CMS make facility level data on race and ethnicity available to help SNFs address inequities. One commenter suggested CMS align SDOH data across all care settings for future health equity measures to ease reporting burden. One commenter suggested CMS prioritize measures that address recurring resident and caregiver complaints as a way to address health inequities. A few commenters expressed concerns about the Program utilizing these types of indices to assess disparities as current measure designs may mask regional and individual disparities. One commenter supported CMS applying points to the Program measures to incentivize improving health equity. One commenter recommended CMS expand the scope of practice for advanced practice providers to help support health equity efforts. A few commenters recommended CMS create domain weights to address health equity as they believe that some measures and data are more impacted by inequity than others.

Response: We will take this feedback into consideration as we develop potential future health equity-related policies.

F. Updates to the Extraordinary Circumstances Exception Policy Regulation Text

In the FY 2019 SNF PPS final rule (83 FR 39280 through 39281), we adopted an Extraordinary Circumstances Exception (ECE) policy for the SNF VBP Program. We have also codified this policy in our regulations at § 413.338(d)(4).

To accommodate the SNF VBP Program's expansion to additional quality measures and apply the ECE policy to those measures, we proposed to update our regulations at § 413.338(d)(4)(v) to remove the specific reference to the SNF Readmission Measure. We proposed that the new language will specify, in part, that we would calculate a SNF performance score for a program year that does not include the SNF's ''performance during the calendar months affected by the extraordinary circumstance.''

We solicited public comment on this proposal.

We did not receive public comments on this provision and therefore, we are finalizing as proposed.

G. Updates to the Validation Processes for the SNF VBP Program

1. Background

Section 1888(h)(12) of the Act requires the Secretary to apply a validation process to SNF VBP Program measures and ''the data submitted under [section 1888(e)(6)] [. . .] as appropriate[. . .].''

We previously finalized a validation approach for the SNFRM and codified that approach at § 413.338(j) of our regulations. In the FY 2023 SNF PPS proposed rule (87 FR 22788 through 22789), we requested comments on the validation of additional SNF measures and assessment data. In the FY 2023 SNF PPS final rule (87 FR 47595 through 47596), we summarized commenters' views and stated that we would take this feedback into consideration as we develop our policies for future rulemaking.

Beginning with the FY 2026 program year, the SNFRM will no longer be the only measure in the SNF VBP Program. We adopted a second claims-based measure, SNF HAI, beginning with that program year and proposed to replace the SNFRM with another claims-based measure, the SNF WS PPR measure, beginning with the FY 2028 program year. We also adopted the DTC PAC SNF measure, another claims-based measure, beginning with the FY 2027 program year and proposed a fourth claims-based measure, Long Stay Hospitalization, beginning with that program year. We adopted the Total Nurse Staffing measure, which is calculated using Payroll Based Journal (PBJ) data, beginning with the FY 2026 program year and proposed to adopt the Nursing Staff Turnover measure, which is also calculated using PBJ data, beginning with the FY 2026 program year. We also proposed to adopt the DC Function and the Falls with Major Injury (Long-Stay) measures calculated using Minimum Data Set (MDS) data beginning with the FY 2027 program year. The addition of measures calculated from these data sources has prompted us to consider the most feasible way to expand our validation program under the SNF VBP Program.

After considering our existing validation process and the data sources for the new measures, and for the reasons discussed more fully below, we proposed to: (1) apply the validation process we previously adopted for the SNFRM to include all claims-based measures; (2) adopt a validation process that applies to SNF VBP measures for which the data source is PBJ data; and (3) adopt a validation process that applies to SNF VBP measures for which

the data source is MDS data. We believe these new validation policies will ensure that the data we use to calculate the SNF VBP measures are accurate for quality measurement purposes.

We note that these new validation policies will apply only to the SNF VBP Program, and we intend to propose a validation process that would apply to the data SNFs report under the SNF QRP, in future rulemaking.

2. Application of the Existing Validation Process for the SNFRM to All Claims-Based Measures Reported in the SNF VBP Program

Beginning with the FY 2026 program year, we will need to validate the SNF HAI measure and beginning with the FY 2027 program year, we will need to validate the Long Stay Hospitalization and DTC PAC SNF measures to meet our statutory requirements. Beginning with the FY 2028 program year, we will also need to validate the SNF WS PPR measure. Therefore, we proposed to expand the previously adopted SNFRM validation process to include all claims-based measures, including the SNF HAI, Long Stay Hospitalization, DTC PAC SNF, and SNF WS PPR measures, as well as any other claims-based measures we may adopt for the SNF VBP Program in the future.

The SNF HAI measure is calculated using Medicare SNF FFS claims data and Medicare inpatient hospital claims data. As discussed in the FY 2023 SNF PPS final rule (87 FR 47590), information reported through claims are validated for accuracy by Medicare Administrative Contractors (MACs) who use software to determine whether billed services are medically necessary and should be covered by Medicare, review claims to identify any ambiguities or irregularities, and use a quality assurance process to help ensure quality and consistency in claim review and processing. They conduct prepayment and post-payment audits of Medicare claims, using both random selection and targeted reviews based on analyses of claims data.

Beginning with the FY 2027 program year, we proposed to adopt the Long Stay Hospitalization measure in the SNF VBP Program. This measure utilizes SNF FFS claims and inpatient hospital claims data. We believe that adopting the existing MAC's process of validating claims for medical necessity through targeted and random audits, as detailed in the prior paragraph, satisfies our statutory requirement to adopt a validation process for the Long Stay Hospitalization measure for the SNF VBP Program.

The DTC PAC SNF measure also uses claims-based data, including data from the ''Patient Discharge Status Code.'' We refer readers to the FY 2023 SNF PPS final rule (87 FR 47577 through 47578) for additional discussion of the data source for the DTC PAC SNF measure. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 52021 through 52029) for a thorough analysis on the accuracy of utilizing the discharge status field. We believe that adopting the existing MAC's process for validating the claims portion of the DTC PAC SNF measure for payment accuracy satisfies our statutory requirement to adopt a validation process for the SNF VBP Program because MACs review claims for medical necessity, ambiguities, and quality assurance through random and targeted reviews, as detailed in the second paragraph of this section.

Beginning with the FY 2028 program year, we proposed to replace the SNFRM with the SNF WS PPR measure. The SNFRM and SNF WS PPR measure utilize the same claims-based data sources. Therefore, the SNFRM's validation process based on data that are validated for accuracy by MACs as detailed in the second paragraph of this section, satisfies the statutory requirement to adopt a validation process for the SNF WS PPR measure for the SNF VBP Program.

We solicited public comment on the proposed application of our previously finalized validation process to all claim-based measures in the SNF VBP Program and also proposed to codify it at § 413.338(j) of our regulations.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to apply our previously finalized validation process to all claim-based measures in the SNF VBP Program.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing the application of our previously finalized validation process to all claims-based measures in the SNF VBP Program.

3. Adoption of a Validation Process That Applies to SNF VBP Measures That Are Calculated Using PBJ Data

Beginning with the FY 2026 program year, the Total Nurse Staffing measure, adopted in the FY 2023 SNF PPS final rule, and the Nursing Staff Turnover measure, are calculated using PBJ data that nursing facilities with SNF beds are already required to report to CMS. PBJ data includes direct care staffing information (including agency and contract staff) based on payroll and other auditable data.[432] CMS conducts quarterly audits aimed at verifying that the staffing hours submitted by facilities are aligned with the hours staff were paid to work over the same timeframe. The PBJ audit process requires selected facilities to submit documentation, that may include payroll, invoice, or contractual obligation data, supporting the staffing hours reported in the PBJ data.[433] This documentation of hours is compared against the reported PBJ staffing hours data and a facility whose audit identifies significant inaccuracies between the hours reported and the hours verified will be presumed to have low levels of staffing. We believe that this existing PBJ data audit process is sufficient to ensure that the PBJ data we use to calculate the Total Nurse Staffing and Nursing Staff Turnover measures are an accurate representation of a facility's staffing. Accordingly, we proposed to adopt that process for purposes of validating SNF VBP measures that are calculated using PBJ data. We also proposed to codify this policy at § 413.338(j) of our regulations.

We solicited public comment on our proposal to adopt the above validation process that applies to measures calculated using the PBJ data.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposed approach to validate PBJ-based measures with existing processes.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing the validation process for SNF VBP measures that are calculated using PBJ data as proposed.

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[432] Centers for Medicare and Medicaid Services. (2022, October 12). *Staffing Data Submission Payroll Based Journal (PBJ). https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/staffing-data-submission-pbj.*

[433] Centers for Medicare and Medicaid (CMS). (2018). *Transition to Payroll-Based Journal (PBJ) Staffing Measures on the Nursing Home Compare tool on Medicare.gov and the Five Star Quality Rating System.* Center for Clinical Standards and Quality/Quality, Safety and Oversight Group. *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-17-NH.pdf.*

4. Adoption of a Validation Process That Applies to SNF VBP Measures That Are Calculated Using MDS Data

We proposed to adopt two MDS measures in the SNF VBP Program, the DC Function and Falls with Major Injury (Long-Stay) measures beginning with the FY 2027 program year/FY 2025 performance period. The MDS is a federally mandated resident assessment instrument that is required to be completed for all residents in a Medicare or Medicaid certified nursing facility, and for residents whose stay is covered under SNF PPS in a non-critical access hospital swing bed facility. The MDS ''includes the resident in the assessment process, and uses standard protocols used in other settings . . . supporting the primary legislative intent that MDS be a tool to improve clinical assessment and supports the credibility of programs that rely on MDS.'' [434] There is no current process to verify that the MDS data submitted by providers to CMS for quality measure calculations is accurate for use in our SNF quality reporting and value-based purchasing programs. While MDS data are audited to ensure accurate payments, we do not believe that this audit process focuses sufficiently on the Program's quality measurement data for use in a quality reporting or value-based purchasing program. While the update to MDS 3.0 was designed to improve the reliability, accuracy, and usefulness of reporting than prior versions,[435] we believe we need to validate MDS data when those data are used for the purpose of a quality reporting or value-based purchasing program. Therefore, we proposed to adopt a new validation method that we will apply to the SNF VBP measures that are calculated using MDS data to meet our statutory requirement. This method is similar to the method we use to validate measures reported by hospitals under the Hospital Inpatient Quality Reporting Program.

We proposed to validate the MDS data used to calculate these measures as follows:

- We proposed to randomly select, on an annual basis, up to 1,500 active and current SNFs, including non-critical access hospital swing bed facilities providing SNF-level services, that submit at least one MDS record in the calendar year 3 years prior to the fiscal year of the relevant program year or were included in the SNF VBP Program in the year prior to the relevant program year. For example, for the FY 2027 SNF VBP Program, we would choose up to 1,500 SNFs that submitted at least one MDS record in calendar year 2024 or were participating in the FY 2026 SNF VBP Program/FY 2024 performance period for validation in FY 2025.
- We proposed that the validation contractor will, for each quarter that applies to validation, request up to 10 randomly selected medical charts from each of the selected SNFs.
- We proposed that the validation contractor will request either digital or paper copies of the randomly selected medical charts from each SNF selected for audit. The SNF will have 45 days from the date of the request (as documented on the request) to submit the requested records to the validation contractor. If the SNF has not complied within 30 days, the validation contractor will send the SNF a reminder to inform the SNF that it must return digital or paper copies of the requested medical records within 45 calendar days following the date of the initial validation contractor medical record request.

We believe the process will be minimally burdensome on SNFs selected to submit up to 10 charts.

We intend to propose a penalty that applies to a SNF that either does not submit the requested number of charts or that we otherwise conclude has not achieved a certain validation threshold in future rulemaking. We also intend to propose in future rulemaking the process by which we would evaluate the submitted medical charts against the MDS to determine the validity of the MDS data used to calculate the measure results. We invited public comment on what that process could include.

We solicited public comments on our proposal to adopt the above validation process for MDS measures beginning with the FY 2027 program year. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed approach to validate MDS-based measures through random audits. One commenter recommended CMS include family and caregiver feedback into the development of this process.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposal to validate MDS data for the SNF QRP to ensure data submitted is not erroneous or incomplete.

Response: We thank the commenters for their support.

Comment: A few commenters who supported validation of MDS data recommended that CMS implement validation of MDS data prior to using MDS-based measures in the SNF VBP Program.

Response: We believe it is not feasible to begin validating MDS data submitted for program years before the FY 2027 SNF VBP program year. We do not believe that delaying the expansion of the SNF VBP Program until MDS data validation is in place is appropriate because MDS-based measures have been used within the SNF QRP for many years. Because SNFs have had extensive experience with MDS-based quality measurement through participation in the SNF QRP, we believe that SNFs have had ample time to ensure the data's accuracy prior to use in the SNF VBP Program and that it is appropriate to move forward with using these measure types in parallel with our implementation of new validation processes.

Comment: A few commenters recommended that CMS not include a penalty for SNFs that fail validation of MDS-based measures because facilities are already penalized through the withholding of funds.

Response: We will take this comment into consideration as we develop additional validation policies for the SNF VBP Program. However, we do not agree that we should hold SNFs harmless for failing validation. We believe that a robust validation program ensures that the most accurate quality data possible are scored for purposes of the SNF VBP Program.

Comment: A few commenters did not support the proposal to validate MDS-based measures. One commenter recommended CMS phase out self-reported measures instead of implementing a validation process. A few commenters expressed that MDS based data are extensively validated through other means (State audits and surveys) and that a new process is an inefficient use of funds. One commenter stated that they believed the rationale for validating MDS-based measures contradicts the rationale used to validate the claims-based measures.

Response: We believe that prioritizing validation for those data submissions already required of SNFs represents a more practical, less burdensome policy for SNFs than adopting new measures to replace MDS-based measurement. MDS data are statutorily required to be submitted to the SNF QRP by SNFs

[434] Centers for Medicare and Medicaid Services (CMS). (2023, March 29). Minimum Data Set (MDS) 3.0 for Nursing Homes and Swing Bed Providers. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqimds30.*

[435] Centers for Medicare and Medicaid Services (CMS). (2023, March 29). Minimum Data Set (MDS) 3.0 for Nursing Homes and Swing Bed Providers. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqimds30.*

under section 1888(e)(6) of the Act. Because SNFs already submit MDS data pursuant to other quality reporting requirements, we believe that MDS-based measures strike an appropriate balance between effective quality measurement and reporting burden.

We recognize that MDS audits are being completed though other means. We believe that these audits, which are effective for their use cases, are insufficient to ensure the accuracy of MDS data elements used for the SNF VBP Program's current and future quality measures. For example, State surveyors may review MDS data to ensure that it meets State standards, which may not align with ensuring the data are accurate for use in the Program's quality measures. We believe that a validation process is needed for the SNF VBP Program that includes auditing the MDS data elements that are used in the measures to ensure the data are accurate. Additionally, we believe that ensuring the Program's data are an accurate representation of a SNFs quality of care is an effective use of funds. Ensuring accurate data means that our beneficiaries can trust the publicly available quality data and make better informed decisions about their care.

We interpret the comment ''contradicting rationale'' to be questioning why the audit of MDS data for payment purposes does not focus sufficiently on the Program's quality measurement data for use in a quality reporting or value-based purchasing program as stated in the proposed rule (88 FR 21398). We note that PBJ measures must be auditable under 42 CFR 483.70[436] and SNF claims and other payment-related information must be audited under section 1983 of the Act. Therefore, we believe that the claims and PBJ measure data elements that are audited for their respective purposes are sufficient with the SNF VBP Program's statutory requirement for validating claims-based and PBJ-based quality measures. For example, the hospitalizations and staffing hours data elements included in the SNF WS PPR, Total Nurse Staffing and Nursing Staff Turnover measures are the core tenets of both their respective measures, and ensuring that claims are valid for payment or ensuring that staffing is capture for regulatory oversite. Although MDS data is audited for other purposes, we feel that a more comprehensive validation process is required for MDS-based quality measures. We further clarify that these existing MDS data audits only review a portion of MDS elements used in the current measures and that the Program's MDS-based quality measures are calculated using data elements that are not consistently reviewed in these audits. We believe that a new validation process is necessary because exiting payment audits do not audit all the MDS data elements needed for the quality measures.

Comment: A few commenters did not support CMS pulling up to 10 charts per SNF as they do not believe it is minimally burdensome.

Response: We proposed this 10-chart maximum because we believe that it strikes the appropriate balance between creating a relatively reliable annual validation estimate with a quantity of charts that are least burdensome to SNFs. The 10 chart maximum is also generally consistent with similar policies we have adopted for the Hospital IQR Program and HAC Reduction Program. For the FY 2026 program year, we request up to 8 charts per quarter for the clinical process of care category of measures and up to 8 charts per quarter for the eCQM category of measures, for a total of up to 16 charts per quarter for the Hospital IQR Program validation, and we request up to 10 charts per quarter for the Hospital-Acquired Condition Reduction Program validation (*https://qualitynet.cms.gov/files/648726a004f753001cd0577b?filename=IP_FY26_ValFactSheet_05082023.pdf*).

After consideration of public comments, we are finalizing the validation process for MDS-based measures in the SNF VBP Program as proposed.

H. SNF Value-Based Incentive Payments for FY 2024

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent of the amounts withheld from SNFs' Medicare payments as required by the SNF VBP Program statute.

We also discussed the process that we undertake for reducing SNFs' adjusted Federal per diem rates under the Medicare SNF PPS and awarding value-based incentive payments in the FY 2019 SNF PPS final rule (83 FR 39281 through 39282).

For the FY 2024 SNF VBP program year, we will reduce SNFs' adjusted Federal per diem rates for the fiscal year by the applicable percentage specified under section 1888(h)(6)(B) of the Act, 2 percent, and will remit value-based incentive payments to each SNF based on their SNF Performance Score, which is calculated based on their performance on the Program's quality measure.

I. Public Reporting on the Provider Data Catalog Website

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make SNFs' performance information on the SNFRM and the SNF WS PPR available to the public on the Nursing Home Compare website or a successor website, and to provide SNFs an opportunity to review and submit corrections to that information prior to its publication. We began publishing SNFs' performance information on the SNFRM in accordance with this provision on October 1, 2017. In December 2020, we retired the *Nursing Home Compare* website and are now using the Provider Data Catalog website (*https://data.cms.gov/provider-data/*) to make quality data available to the public, including SNF VBP performance information. We will begin publishing performance information on the SNF WS PPR measure when that measure is implemented beginning in the FY 2028 program year.

Additionally, section 1888(h)(9)(A) of the Act requires the Secretary to make available to the public certain information on SNFs' performance under the SNF VBP Program, including their SNF Performance Scores and rankings. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the Program, including the range of SNF Performance Scores and the number of SNFs receiving value-based incentive payments, and the range and total amount of those payments.

In the FY 2017 SNF PPS final rule (81 FR 52006 through 52009), we discussed the statutory requirements governing confidential feedback reports and public reporting of SNFs' performance information under the SNF VBP Program and finalized our two-phased review and correction process. In the FY 2018 SNF PPS final rule (82 FR 36621 through 36623), we finalized additional requirements for phase two of our review and correction process, a policy to publish SNF VBP Program performance information on the *Nursing Home Compare* or a successor website after SNFs have had the opportunity to review and submit corrections to that information. In that final rule, we also

[436] CMS. (June 2022). *Electronic Staffing Data Submission Payroll-Based Journal. https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/downloads/pbj-policy-manual-final-v25-11-19-2018.pdf.*

finalized the requirements to rank SNFs and adopted data elements that are included in the ranking to provide consumers and interested parties with the necessary information to evaluate SNF's performance under the Program. In the FY 2020 SNF PPS final rule (84 FR 38823 through 38825), we finalized a policy to suppress from public display SNF VBP performance information for low-volume SNFs and finalized updates to the phase one review and correction deadline. In the FY 2021 SNF PPS final rule (85 FR 47626 through 47627), we finalized additional updates to the phase one review and correction deadline. In the FY 2022 SNF PPS final rule (86 FR 42516 through 42517), we finalized a phase one review and correction claims ''snapshot'' policy. In the FY 2023 SNF PPS final rule (87 FR 47591 through 47592), we finalized updates to our data suppression policy for low-volume SNFs due to the addition of new measures and case and measure minimum policies.

IX. Civil Money Penalties: Waiver of Hearing, Automatic Reduction of Penalty Amount

Section 488.436 provides a facility the option to waive its right to a hearing in writing and receive a 35 percent reduction in the amount of civil money penalties (CMPs) owed in lieu of contesting the enforcement action. This regulation was first adopted in a 1994 final rule (59 FR 56116, 56243), with minor corrections made to the regulation text in 1997 (62 FR 44221) and in 2011 (76 FR 15127) to implement section 6111 of the Affordable Care Act of 2010. Over the years, we have observed that most facilities who have been imposed CMPs do not request a hearing to appeal the survey findings of noncompliance on which their CMPs are based.

In CY 2016, 81 percent of LTC facilities submitted a written waiver of a hearing and an additional 15 percent of facilities did not submit a waiver although they did not contest the penalty and its basis. Only 4 percent of facilities availed themselves of the full hearing process. The data from CY 2018 and CY 2019 stayed fairly consistent with 80 percent of facilities submitting a written waiver of a hearing and 14 percent of facilities not submitting the waiver nor contesting the penalty and its basis. Only 6 percent of facilities availed themselves of the full hearing process. In CY 2020, 81 percent of facilities submitted a written waiver of the hearing, 15 percent of facilities did not submit a waiver nor contest the penalty and its basis, and only 4 percent of facilities availed themselves of the full hearing process. In CY 2021, 91 percent of facilities submitted a written waiver of the hearing, 7 percent of facilities did not submit the waiver nor contest the penalty and its basis, and only 2 percent of facilities utilized the full hearing process. Data from CY 2022 continues this trend showing that 81 percent of LTC facilities submitted a written waiver of their hearing rights and 17 percent of facilities did not submit a waiver of appeal rights but did not contest the penalty nor its basis. Again, only 2 percent of facilities availed themselves of the full hearing process in CY 2022. Therefore, based on our experience with LTC facilities with imposed CMPs and the input provided by our CMS Locations (formerly referred to as Regional Offices) that impose and collect CMPs, we proposed to revise these requirements at § 488.436 by creating a constructive waiver process.

Specifically, we proposed to revise the current written waiver process to allow a constructive waiver that retains the accompanying 35 percent penalty reduction, however, we will revisit the appropriateness of that penalty reduction in a future rulemaking, if warranted, as discussed further below. Removal of the facility's requirement to submit a separate written request to waive their right to appeal would result in a cost and time savings for CMS, which currently receives and processes these waivers. This will allow CMS to reallocate this time and funding currently spent processing these waivers to bolstering other oversight and enforcement activities, including providing additional focus on nursing home compliance, as well as to cases involving facilities that choose to contest our findings through the Departmental Appeals Board. Current budgetary constraints have tightened oversight and enforcement resources, in addition to the survey and enforcement backlog resulting from the COVID–19 PHE.

We proposed to amend the language at § 488.436(a) by eliminating the requirement to submit a written waiver and create in its place a constructive waiver process that would operate by default when a timely request for a hearing has not been received. Facilities that wish to request a hearing to contest the noncompliance leading to the imposition of the CMP would continue to follow all applicable appeals process requirements, including those at § 498.40, as currently referenced at § 488.431(d).

Specifically, we proposed to revise § 488.436(a) to state that a facility is deemed to have waived its rights to a hearing if the time period for requesting a hearing has expired and request for a hearing has not been received within the requisite submission time. We have observed that many facilities submitting a request for a waiver of hearing wait until close to the end of the 60-day timeframe within which a waiver must be submitted, thus delaying the ultimate due date of the CMP amount. Under this proposed process, the 35 percent reduction would be applied after the 60-day timeframe.

Given our finalized policy of removing the requirement to actively waive their right to a hearing, we will revisit the appropriateness of that penalty reduction, if warranted by the review, in a future rulemaking. The move to a constructive waiver process in this rule purely reflects the need to reduce costs and paperwork burden for CMS to prioritize current limited Survey and Certification resources for enforcement actions, and we will consider whether the existing penalty reduction is appropriate given this final policy.

We also note that we continue to have the opportunity under § 488.444, to settle CMP cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which our enforcement action prevails, in accordance with § 488.30. This provides the opportunity to settle a case, when warranted, even if the facility's hearing right was not previously waived. Even if a hearing had been requested, if all parties can reach an agreement over deficiencies to be corrected and the CMP to be paid until corrections are made (for example, CMS agrees to lower a CMP amount based on actions the facility has taken to protect resident health and safety), then costly hearing procedures could be avoided. We believe that eliminating the current requirements for a written waiver at § 488.436 will not negatively impact facilities.

In addition to the changes to § 488.436(a), we proposed corresponding changes to §§ 488.432 and 488.442 which currently reference only the written waiver process. We proposed to make conforming changes that establish that a facility is considered to have waived its rights to a hearing if the time period for requesting a hearing has expired, in lieu of a written waiver of appeal rights. Finally, we note that the current requirements at § 488.436(b) would remain unchanged. At the same time, CMS commits to studying its procedures for reviewing and processing waivers and as necessary modernizing those procedures to reduce the amount of time

required for documentation review of CMPs.

The proposed revisions were previously proposed and published in the July 18, 2019 proposed rule entitled, ''Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency'' (84 FR 34737, 34751). Although on July 14, 2022, we announced an extension of the timeline for publication of the final rule for the 2019 proposals (*see* 87 FR 42137), we are withdrawing that proposal revising § 488.436 and we re-proposed the revisions for a facility to waive its hearing rights in an effort to gather additional feedback from interested parties (*see* FY 2024 SNF PPS proposed rule (88 FR 21316)). While this regulatory action is administrative in nature, in the future, we may assess whether the 35 percent penalty reduction is functioning as intended to make the civil money penalties administrative process more efficient, or whether a lesser penalty reduction is warranted.

We solicited comments from the public addressing any potential circumstances in which facilities' needs or the public interest could best be met or only be met by the use of a written waiver. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: While the majority of comments received supported the constructive waiver, we did receive several comments opposing the constructive waiver provision. One commenter was concerned that if facilities are no longer required to proactively request a waiver to receive the reduction, there is no longer any corporate acknowledgement that a wrong has occurred that resulted in the penalty. The commenter stated that the reduced penalties would become a cost of doing business. Another commenter stated that the Federal nursing home regulations are the minimum standards LTC facilities agree to meet. The commenter stated that when a facility is issued a deficiency for a violation of those minimum standards, they should not automatically be given a 35 percent reduction solely because they decided to not appeal the deficiency finding, as CMPs are meant to be a deterrent and penalize LTC facilities who have violated the minimum requirements for participation. The commenter stated that an automatic 35 percent reduction serves as a reward to those facilities who flout the minimum standards and have actually been cited at actual harm or immediate jeopardy. Many commented that CMS already imposes comparatively few CMPs because, as a matter of policy, it generally limits CMPs to deficiencies that are cited for causing actual harm or putting residents in immediate jeopardy classifications of severity applied to less than 4 percent of all deficiencies observed in facility surveys. Some commenters stated that most deficiencies have no financial consequence, no matter how serious the harm to residents. They further stated that CMS provides no real rationale for the proposed rule, which creates a financial windfall of millions of dollars for LTC facilities. They were concerned that this is a signal to SNFs that compliance with regulations is not mandatory and effectively reduces the enforcement efforts of CMS. Another commenter stated that the financial repercussions facilities may face for violating regulations incentivize better care. Eliminating the requirement that facilities waive their rights to challenge CMS findings removes an incentive for facilities to comply with the regulations.

Response: We appreciate the comments raised, but we believe clarification and modernization to improve efficiencies are warranted on the current waivers process. In CY 2022, 81 percent of LTC facilities submitted a written waiver of the hearing and 17 percent of facilities did not submit a waiver but did not contest the penalty and its basis. Only 2 percent of facilities actually contested the imposed penalty and its basis. The majority of facilities are already submitting a waiver, as is currently required, and receiving the reduction; consequently, the revision to the regulation would not have a significant effect on the amount of CMPs being collected. The constructive waiver process would not affect the frequency of CMPs being imposed, CMS' ability to penalize facilities for infractions, or the publication of facility infractions through Care Compare. We believe that by improving program efficiencies we will be able to divert these resources to strengthening other oversight and enforcement activities. We also note that facilities that waive their right to a hearing may have many reasons for doing so, and the removal of this active waiver requirement is in no way an indication that we are reducing necessary oversight and enforcement activities. We note that the penalty, and the citation that led to the imposition of the penalty, will continue to be posted on Care Compare and indicate that the facility was not in compliance. This will remain the case irrespective of whether the appeal is waived affirmatively or constructively.

Moreover, as stated previously in this section of the final rule, we believe that the subsequent administrative savings from not processing written waivers would allow us to reallocate those resources to activities ensuring the health and safety of residents. However, in light of the comments submitted around the constructive waiver and the changes to the waiver process, we plan to review the appropriateness of the 35 percent penalty reduction in future rulemaking. After consideration of public comments, we are finalizing our proposed changes to the civil money penalty reduction process without modifications.

X. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rule issued.

In this case, we identified the need for additional conforming changes to the regulatory text after this rule was already proposed, as described in section V.D. of this proposed rule. The conforming changes are minor and necessary to implement the statute. Specifically, in the proposed rule, we revised the regulation text to implement the requirement under section 4121(a)(4) of Division FF of the CAA, 2023 to exclude marriage and family therapist (MFT) services and mental health counselor services (MHC) from SNF consolidated billing for services furnished on or after January 1, 2024. Subsequently, we identified the need for additional conforming changes to the regulatory text. In addition to adding the two new exclusions themselves to the regulation text as set forth in the proposed rule (and as described in section V.D. of this final rule), the existing exclusion for certain telehealth services needs to be revised as well, because it cross-refers to subparagraphs that are now being renumbered as a result of adding the new exclusions. Specifically, a conforming change is needed in the consolidated billing exclusion provision on telehealth services at existing § 411.15(p)(2)(xii) (which, as a result of the other

regulation text changes finalized in this rule, will be redesignated § 411.15(p)(2)(xiv)) and in the parallel provider agreement provision on telehealth services at existing § 489.20(s)(12) (which, as a result of the other regulation text changes finalized in this rule, will be redesignated § 489.20(s)(14)). Because these inadvertently omitted additional provisions implement statutory language without any exercise of discretion by the Secretary, we have determined that it would be unnecessary and contrary to public interest to rely on another notice-and-comment period to issue them. We are simply correcting oversights to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment.

XI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment (see section IX.D. of the FY 2024 SNF PPS proposed rule) on each of the aforementioned issues for the following sections of the rule that contained information collection requirements.

A. Wage Estimates

To derive average private sector costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 24 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. See Table 25 for an estimate of the composite wage associated with removing the Application of Functional Assessment/Care Plan measure. See Table 26 for an estimate of the composite wage associated with adopting the Patient/Resident COVID 19 Vaccine measure.

TABLE 24—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Licensed Vocational Nurse (LVN)	29–2061	24.93	24.93	49.86
Occupational Therapist (OT)	29–1122	43.02	43.02	86.04
Physical Therapist (PT)	29–1123	44.67	44.67	89.34
Registered Nurse (RN)	29–1141	39.78	39.78	79.56
Speech Language Pathologist (SLP)	29–1127	41.26	41.26	82.52

As mentioned, we have adjusted the private sector's employee hourly wage by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Skilled Nursing Facility Quality Reporting Program (SNF QRP)

When ready, we intend to account for the following changes under the standard non-rule PRA process that consists of publishing 60- and 30-day **Federal Register** notices that solicit comment from the public. Consistent with this final rule, the notices will be associated with OMB control number 0938–1140 (CMS–10387). The notices will account for the changes identified in Tables 28 and 29 and changes to MDS (the minimum data set).

In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2-percentage points the otherwise applicable annual payment update to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year.

In the SNF FY 2024 PPS proposed rule (88 FR 21332 through 21354), we proposed to modify one measure, adopt three new measures, and remove three measures from the SNF QRP. In the SNF FY 2024 PPS proposed rule (88 FR 21360), we also proposed to increase the data completion thresholds for the MDS items. We discussed in detail these information collections in the SNF FY 2024 PPS proposed rule (88 FR 21400). As discussed in section VI.C.2.a.(5) of this final rule, we are not finalizing the CoreQ: SS DC measure for the SNF QRP. Consequently, the ICRs related to the CoreQ: SS DC measure proposal are omitted from this final rule.

As stated in section VII.C.1.a. of this final rule, we proposed to modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP COVID–19 Vaccine) measure beginning with the FY 2025 SNF QRP. While we are not making any changes to the data submission process for the HCP COVID–19 Vaccine measure, we are requiring that for purposes of meeting FY 2025 SNF QRP compliance, SNFs will report data on the measure using the modified numerator definition for at least one self-selected week during each month of the reporting quarter beginning with reporting period of the 4th quarter of CY 2023. Under this requirement, SNFs will continue to report data for the HCP COVID–19 Vaccine measure to the CDC's National Healthcare Safety Network (NHSN) for at least one self-selected week during each month of the

reporting quarter. The burden associated with the HCP COVID–19 Vaccine measure is accounted for under OMB control number 0920–1317, entitled ''[NCEZID] National Healthcare Safety Network (NHSN) Coronavirus (COVID–19) Surveillance in Healthcare Facilities.'' Because we are not making any updates to the form, manner, and timing of data submission for this measure, we are not making any changes to the currently approved (active) requirements or burden estimates under control number 0920–1317. See the FY 2022 SNF PPS final rule (86 FR 42480 through 42489) for a discussion of the form, manner, and timing of data submission of this measure.

As a result of our decision to not adopt the CoreQ: SS DC measure, in this final rule, we are adopting two (instead of three) new measures and removing three measures from the SNF QRP. We present the burden associated with these proposals in the same order they were proposed in the SNF FY 2024 PPS proposed rule (88 FR 21332 through 21354).

As stated in section VII.C.1.b. of this final rule, we proposed to adopt the Discharge Function Score (DC Function) measure beginning with the FY 2025 SNF QRP. This assessment-based quality measure will be calculated using data from the minimum data set (MDS) that are already reported to the Medicare program for payment and quality reporting purposes. The burden is currently approved by OMB under control number 0938–1140 (CMS–10387). Under this requirement, there will be no additional burden for SNFs since it does not require the collection of new or revised data elements.

As stated in section VII.C.1.c. of this final rule, we proposed to remove the Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (Application of Functional Assessment/Care Plan) measure beginning with the FY 2025 SNF QRP. We believe that the removal of the measure will result in a decrease of 18 seconds (0.3 minutes or 0.005 hrs) of clinical staff time at admission beginning with the FY 2025 SNF QRP. We believe that the MDS item affected by the removal of the Application of Functional Assessment/Care Plan measure is completed by Occupational Therapists (OT), Physical Therapists (PT), Registered Nurses (RN), Licensed Practical and Licensed Vocational Nurses (LVN), and/or Speech-Language Pathologists (SLP) depending on the functional goal selected. We identified the staff type per MDS item based on past SNF burden calculations. Our assumptions for staff type were based on the categories generally necessary to perform an assessment, however, individual SNFs determine the staffing resources necessary. Therefore, we averaged BLS' National Occupational Employment and Wage Estimates (See Table 25) for these labor types and established a composite cost estimate using our adjusted wage estimates. The composite estimate of $86.21/hr was calculated by weighting each hourly wage based on the following breakdown regarding provider types most likely to collect this data: OT 45 percent at $86.04/hr; PT 45 percent at $89.34/hr; RN 5 percent at $79.56/hr; LVN 2.5 percent at $49.86/hr; and SLP 2.5 percent at $82.52/hr.

For the purpose of deriving the composite wage we also estimated 2,406,401 admission assessments from 15,471 SNFs annually.

TABLE 25—ESTIMATED COMPOSITE WAGE AND BURDEN FOR REMOVING THE APPLICATION OF FUNCTIONAL ASSESSMENT/CARE PLAN MEASURE

Occupation title	Occupation code	Adjusted hourly wage ($/hr)	Percent of assessments collected	Number of assessments collected *	Total time (hours)	Total cost ($)
Occupational Therapist (OT)	29–1122	86.04	45	1,082,880.5	5,414	465,855
Physical Therapist (PT)	29–1123	89.34	45	1,082,880.5	5,414	483,723
Registered Nurse (RN)	29–1141	79.56	5	120,320	602	47,863
Licensed Vocational Nurse (LVN)	29–2061	49.86	2.5	60,160	301	14,998
Speech Language Pathologist (SLP)	29–1127	82.52	2.5	60,160	301	24,822
Total	n/a	n/a	100	2,406,401	12,032	1,037,261
Composite Wage	$1,037,261/12,032 hrs = $86.2085/hr					

For removing the Application of Functional Assessment/Care Plan measure, we estimate an annual decrease of minus 12,032 hours (0.005 hr × 2,406,401 admission assessments) and minus $1,037,261 (12,032 hours × $86.2085/hr) for all SNFs.

As stated in section VII.C.1.d. of this final rule, we proposed to remove the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Self-Care Score) measure as well as the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (Change in Mobility Score) measure beginning with the FY 2025 SNF QRP. While these assessment-based quality measures were proposed for removal, the data elements used to calculate the measures will still be reported by SNFs for other payment and quality reporting purposes. Therefore, we believe that the removal of the Change in Self-Care Score and Change in Mobility Score measures will not have any impact on our currently approved reporting burden for SNFs.

As stated in section VII.C.2.b. of this final rule, we proposed to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure beginning with the FY 2026 SNF QRP. This assessment-based quality measure will be collected using the MDS. One data element will be added to the MDS at discharge to allow for the collection of the Patient/Resident COVID–19 Vaccine measure. We believe this will result in an increase of 18 seconds (0.3 minutes or 0.005 hrs) of clinical staff time at discharge beginning with the FY 2026 SNF QRP. We believe that the added data element for the Patient/Resident COVID–19 Vaccine measure will be completed equally by an RN (0.0025 hr = 0.005 hr/2) and LVN (0.0025 hr = 0.005/2), however, individual SNFs determine the staffing resources necessary. Therefore, we averaged BLS' National Occupational Employment and Wage Estimates (see Table 26) for these labor types and established a composite cost estimate using our adjusted wage estimates. The

composite estimate of $64.71/hr (see Table 26) was calculated by weighting each hourly wage based on the following breakdown regarding provider types most likely to collect this data: RN 0.0025 hr at $79.56/hr and LVN 0.0025 hr at $49.86/hr.

For purposes of deriving the burden impact, we estimated a total of 2,406,401 discharges from 15,471 SNFs annually.

TABLE 26—ESTIMATED COMPOSITE WAGE FOR ADOPTING THE PATIENT/RESIDENT COVID–19 VACCINE MEASURE

Occupation title	Occupation code	Adjusted hourly wage ($/hr)	Percent of assessments collected	Number of assessments collected *	Total time (hours)	Total cost ($)
Registered Nurse (RN)	29–1141	79.56	50	1,203,200.5	6,016	478,633
Licensed Vocational Nurse (LVN)	29–2061	49.86	50	1,203,200.5	6,016	299,958
Total	n/a	n/a	100	2,406,401	12,032	778,591
Composite Wage	$778,591/12,032 hours = $64.71/hr					

We estimate the total burden for complying with the SNF QRP requirements will increase by 12,032 hours (0.005 hr × 2,406,401 discharge assessments) and $778,591 (12,032 hrs × $64.71/hr) for all SNFs annually based on the adoption of the Patient/Resident COVID–19 Vaccine measure.

In summary, we estimate the updated SNF QRP changes associated with the removal of the Application of Functional Assessment/Care Plan measure and the adoption of Patient/Resident COVID–19 measure will have a net zero effect on the total time to complete an MDS but will result in a decrease of $258,670 for all SNFs annually (see Table 27).

TABLE 27—SUMMARY OF SNF QRP BURDEN CHANGES

Requirement	Number of respondents	Total responses	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)
Removal of the Application of Functional Assessment/Care Plan measure beginning with the FY 2025 SNF QRP.	15,471 SNFs	(2,406,401)	(0.005)	(12,032)	Varies	(1,037,261)
Adoption of the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 SNF QRP.	15,471 SNFs	2,406,401	0.005	12,032	Varies	778,591
Total Change	n/a	0	0	0	n/a	(258,670)

As stated in section VII.F.5. of this final rule, we proposed to increase the SNF QRP data completion thresholds for MDS data items beginning with the FY 2026 SNF QRP. SNFs will be required to report 100 percent of the required quality measures data and standardized patient assessment data collected using the MDS on at least 90 percent of the assessments they submit through the CMS designated submission system. SNFs have been required to submit MDS quality measures data and standardized patient assessment data for the SNF QRP since October 1, 2016. Since our data indicates that the majority of SNFs are already in compliance with, or exceeding this threshold, we are not making any changes to the burden that is currently approved by OMB under control number 0938–1140 (CMS–10387).

2. ICRs Regarding the Skilled Nursing Facility Value-Based Purchasing Program

In section VIII.B.3. of this final rule, we are replacing the SNFRM with the SNF WS PPR measure beginning with the FY 2028 SNF VBP program year. The measure is calculated using Medicare FFS claims data, which are the same data we use to calculate the SNFRM, and therefore, this measure will not create any new or revised burden for SNFs.

We are also adopting four new quality measures in the SNF VBP Program as discussed in section VIII.B.4. of this final rule. One of the measures is the Total Nursing Staff Turnover Measure beginning with the FY 2026 SNF VBP program year. This measure is calculated using PBJ data that nursing facilities with SNF beds currently report to us as part of the Five Star Quality Rating System, and therefore, this measure will not create new or revised burden for SNFs. We are also adopting three additional quality measures beginning with the FY 2027 SNF VBP program year: (1) Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) Measure (''Falls with Major Injury (Long-Stay) measure''), (2) Skilled Nursing Facility Cross-Setting Discharge Function Score Measure (''DC Function measure''), and (3) Number of Hospitalizations per 1,000 Long-Stay Resident Days Measure (''Long-Stay Hospitalization measure''). The Falls with Major Injury (Long-Stay) measure and the DC Function measure are calculated using MDS 3.0 data and are calculated by us under the Nursing Home Quality Initiative and SNF QRP Program, respectively. The Long-Stay Hospitalization measure is calculated using Medicare FFS claims data. Therefore, these three measures will not create new or revised burden for SNFs.

Furthermore, in section VIII.G. of this final rule, we are updating the validation process for the SNF VBP Program, including adopting a new process for the Minimum Data Set (MDS) measures beginning with the FY 2027 SNF VBP program year. As finalized, we will validate data used to calculate the measures used in the SNF VBP Program, and 1,500 randomly selected SNFs a year would be required to submit up to 10 charts that would be used to validate the MDS measures.

Finally, in section VIII.E.4. of this final rule, we are adopting a Health Equity Adjustment beginning with the

FY 2027 SNF VBP program year. The source of data we would use to calculate this adjustment is the State Medicare Modernization Act (MMA) file of dual eligibility, and therefore our calculation of this adjustment would not create any additional reporting burden for SNFs.

The aforementioned FFS-related claims submission requirements and burden, which are previously mentioned in the preceding paragraphs, are active and approved by OMB under control number 0938–1140 (CMS–10387). The aforementioned MDS submission requirements and burden are active and approved by OMB under control number 0938–1140 and the burden associated with the items used to calculate the measures is already accounted for in the currently approved information collection since it is used for the SNF QRP. The aforementioned PBJ submission requirements and burden are PRA exempt (as are all nursing home requirements for participation). The increase in burden for the SNFs would be accounted for in the submission of up to 10 charts for review, and the proposed process would not begin until FY 2025. The required 60-day and 30-day notices would be published in the **Federal Register** and the comment periods would be separate from those associated with this rulemaking. This rule's changes will have no impact on any of the requirements and burden that are currently approved under these control numbers.

3. ICRs Regarding Civil Money Penalties: Waiver of Hearing, Automatic Reduction of Penalty Amount

This rule finalizes our proposal to eliminate the requirement for facilities facing a civil money penalty to actively waive their right to a hearing in writing to receive a penalty reduction. We are creating, in its place, a constructive waiver process that will operate by default when CMS has not received a timely request for a hearing. While OBRA '87 exempts the waiver requirements and burden from the PRA, the requirements and burden are scored under the RIA section of this preamble.''

C. Summary of Finalized Requirements and Associated Burden Estimates

TABLE 28—SUMMARY OF BURDEN ESTIMATES FOR FY 2025

Regulatory section(s) under Title 42 of the CFR	OMB control No. (CMS ID No.)	Number of respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)
413.360(b)(1)	0938–1140 ..... CMS–10387	15,471 SNFs	(2,406,401)	0.005	(12,032)	86.21	(1,037,261)

TABLE 29—SUMMARY OF BURDEN ESTIMATES FOR FY 2026

Regulatory section(s) under Title 42 of the CFR	OMB control No. (CMS ID No.)	Number of respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost ($)
413.360	0938–1140 CMS–10387	15,471 SNFs	2,406,401	0.005	12,032	79.56	778,591

XII. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

a. Statutory Provisions

This rule updates the FY 2024 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted Federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. These are statutory provisions that prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, and we do not have the discretion to adopt an alternative approach on these issues.

With respect to the SNF QRP, this final rule finalizes updates beginning with the FY 2025 and FY 2026 SNF QRP. Specifically, we adopt a modification to a current measure in the SNF QRP beginning with the FY 2025 SNF QRP, which we believe will encourage healthcare personnel to remain up to date with the COVID–19 vaccine, resulting in fewer cases, less hospitalizations, and lower mortality associated with the virus. We adopt two new measures: (1) one to satisfy the requirement set forth in sections 1888(e)(6)(B)(i)(II) and 1899B(c)(1)(A) of the Act which would replace the current cross-setting process measure with one more strongly associated with desired patient functional outcomes beginning with the FY 2025 SNF QRP; and (2) one that supports the goals of CMS Meaningful Measures Initiative 2.0 to empower consumers, as well as assist SNFs leverage their care processes to increase vaccination coverage in their settings to protect residents and prevent negative outcomes beginning with the FY 2026 SNF QRP. We finalize the removal of three measures from the SNF QRP, beginning with the FY 2025 SNF QRP, as they meet the criteria specified at § 413.360(b)(2) for measure removal. We further finalize an increase to the data completion threshold for Minimum Data Set (MDS) data items, beginning with the FY 2026 SNF QRP, which we believe will improve our ability to appropriately analyze quality measure data for the purposes of monitoring SNF outcomes. For consistency in our regulations, we also finalize conforming revisions to the requirements related to these proposals under the SNF QRP at § 413.360.

With respect to the SNF VBP Program, this final rule updates the SNF VBP Program requirements for FY 2024 and subsequent years. Section 1888(h)(2)(A)(ii) of the Act (as amended by section 111(a)(2)(C) of the CAA 2021) allows the Secretary to add up to nine new measures to the SNF VBP Program. We are finalizing four new measures for the SNF VBP Program. We are finalizing one new measure beginning with the FY 2026 SNF VBP program year and three new measures beginning with the FY 2027 program year. We are also replacing the SNFRM with the SNF WS PPR measure beginning with the FY

2028 SNF VBP Program year. Additionally, to better address health disparities and achieve health equity, we are finalizing a Health Equity Adjustment (HEA) beginning with the FY 2027 program year. As part of the HEA, we are finalizing a variable payback percentage (for additional information on the HEA and the fluctuating payback percentage see section VII.E.4. of the proposed rule). Section 1888(h)(3) of the Act requires the Secretary to establish and announce performance standards for SNF VBP Program measures no later than 60 days before the performance period, and this final rule includes numerical values of the performance standards for the SNFRM, the SNF Healthcare-Associated Infection Requiring Hospitalization (SNF HAI), Total Nurse Staffing, Nursing Staff Turnover, and the Discharge to Community—Post-Acute Care (DTC PAC SNF) measures. Section 1888(h)(12)(A) of the Act requires the Secretary to apply a validation process to SNF VBP Program measures and ''the data submitted under [section 1888(e)(6)] [. . .] as appropriate[. . .].'' We are finalizing a new validation process for measures beginning in the FY 2027 program year.

b. Discretionary Provisions

In addition, this final rule includes the following discretionary provisions:

(1) PDPM Parity Adjustment Recalibration

In the FY 2023 SNF final rule (87 FR 47502), we finalized a recalibration of the PDPM parity adjustment with a 2-year phase-in period, resulting in a reduction of 2.3 percent, or $780 million, in FY 2023 and a planned reduction in FY 2024 of 2.3 percent. We finalized the phased-in approach to implementing this adjustment based on a significant number of comments supporting this approach. Accordingly, we are implementing the second phase of the 2-year phase-in period, resulting in a reduction of 2.3 percent, or approximately $789 million, in FY 2024.

(2) SNF Forecast Error Adjustment

Each year, we evaluate the SNF market basket forecast error for the most recent year for which historical data is available. The forecast error is determined by comparing the projected SNF market basket increase in a given year with the actual SNF market basket increase in that year. In evaluating the data for FY 2022, we found that the forecast error for FY 2022 was 3.6 percentage points, exceeding the 0.5 percentage point threshold we established in regulation for proposing adjustments to correct for forecast error. Given that the forecast error exceeds the 0.5 percentage point threshold, current regulations require that the SNF market basket percentage increase for FY 2024 be adjusted upward by 3.6 percentage points to account for forecasting error in the FY 2022 SNF market basket update.

(3) Technical Updates to ICD–10 Mappings

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the PDPM, effective October 1, 2019. The PDPM utilizes ICD–10 codes in several ways, including using the patient's primary diagnosis to assign patients to clinical categories under several PDPM components, specifically the PT, OT, SLP and NTA components. In this rule, we finalize several substantive changes to the PDPM ICD–10 code mapping.

(4) Civil Money Penalties: Waiver of Hearing, Automatic Reduction of Penalty Amount

We are finalizing our proposal to eliminate the requirement for facilities to actively waive their right to a hearing in writing and create in its place a constructive waiver process that would operate automatically when CMS has not received a timely request for a hearing. At this time, the accompanying 35 percent penalty reduction will remain, but we will review the appropriateness of this reduction and, if warranted by the review, adjust it in a future rulemaking. The accompanying 35 percent penalty reduction will remain. This revision eliminating the LTC requirement to submit a written request for a reduced penalty amount when a hearing has been waived will simplify and streamline the current requirement, while maintaining a focus on providing high quality care to residents. This provision will also ease the administrative burden for facilities that are currently submitting waiver requests to CMS locations. In CY 2022, 81 percent of facilities facing CMPs filed an appeal waiver while only 2 percent of facilities filed an appeal of their CMP with the Departmental Appeals Board. The remaining 17 percent of facilities neither waived nor timely filed an appeal. We estimate that moving to a constructive waiver process will eliminate the time and paperwork necessary to complete and send in a written waiver and will thereby result, as detailed below, in a total annual savings of $2,299,716 in administrative costs for LTC facilities facing CMPs ($861,678 + $1,438,038 = $2,299,716). Ultimately, this provision will reduce administrative burden for facilities and for CMS.

2. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's

Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the $200 million or more in any 1 year, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

3. Overall Impacts

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2023 (87 FR 47502). We estimate that the aggregate impact will be an increase of approximately $1.4 billion (4.0 percent) in Part A payments to SNFs in FY 2024. This reflects a $2.2 billion (6.4 percent) increase from the update to the payment rates and a $789 million (2.3 percent) decrease as a result of the second phase of the parity adjustment recalibration. We note in this final rule that these impact numbers do not incorporate the SNF VBP Program reductions that we estimate would total $184.85 million in FY 2024. We note that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and (e)(5) of the Act and implementing regulations at § 413.337(d), we are updating the FY 2023 payment rates by a factor equal to the market basket percentage increase adjusted for the forecast error adjustment and reduced by the productivity adjustment to determine the payment rates for FY 2024. The impact to Medicare is included in the total column of Table 30. The annual update in this rule applies to SNF PPS payments in FY 2024. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2024 SNF PPS payment impacts appear in Table 30. Using the most recently available data, in this case FY 2022 we apply the current FY 2023 CMIs, wage index and labor-related share value to the number of payment days to simulate FY 2023 payments. Then, using the same FY 2022 data, we apply the FY 2024 CMIs, wage index and labor-related share value to simulate FY 2024 payments. We tabulate the resulting payments according to the classifications in Table 30 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2023 payments to the simulated FY 2024 payments to determine the overall impact. The breakdown of the various categories of data in Table 30 is as follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various changes contained in this final rule on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the second phase of the parity adjustment recalibration discussed in section IV.C. of this rule.
- The fourth column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available as well as accounts for the 5 percent cap on wage index transitions. The total impact of this change is 0.0 percent; however, there are distributional effects of the change.
- The fifth column shows the effect of all of the changes on the FY 2024 payments. The update of 6.4 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments would increase by 6.4 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 30, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this final rule, rural providers would experience a 3.0 percent increase in FY 2024 total payments.

In this chart and throughout the rule, we use a multiplicative formula to derive total percentage change. This formula is:

(1 + Parity Adjustment Percentage) * (1 + Wage Index Update Percentage) * (1 + Payment Rate Update Percentage) − 1 = Total Percentage Change

For example, the figures shown in Column 5 of Table 30 are calculated by multiplying the percentage changes using this formula. Thus, the Total Change figure for the Total Group Category is 4.0 percent, which is (1 − 2.3%) * (1 + 0.0%) * (1 + 6.4%) −1.

As a result of rounding and the use of this multiplicative formula based on percentages, derived dollar estimates may not sum.

TABLE 30—IMPACT TO THE SNF PPS FOR FY 2024

Impact categories	Number of facilities	Parity adjustment recalibration (%)	Update wage data (%)	Total change (%)
Group				
Total	15,503	−2.3	0.0	4.0
Urban	11,254	−2.3	0.1	4.1
Rural	4,249	−2.2	−0.7	3.3
Hospital-based urban	366	−2.3	0.0	4.0
Freestanding urban	10,888	−2.3	0.1	4.1
Hospital-based rural	378	−2.2	−0.3	3.7

TABLE 30—IMPACT TO THE SNF PPS FOR FY 2024—Continued

Impact categories	Number of facilities	Parity adjustment recalibration (%)	Update wage data (%)	Total change (%)
Freestanding rural	3,871	−2.2	−0.7	3.3
Urban by region				
New England	734	−2.3	−0.7	3.2
Middle Atlantic	1,471	−2.4	1.4	5.3
South Atlantic	1,945	−2.3	0.1	4.1
East North Central	2,181	−2.3	−0.7	3.2
East South Central	555	−2.2	0.0	4.0
West North Central	958	−2.3	−0.4	3.6
West South Central	1,454	−2.3	0.0	4.0
Mountain	546	−2.3	−0.9	3.0
Pacific	1,404	−2.4	0.1	4.0
Outlying	6	−2.0	−2.6	1.6
Rural by region				
New England	117	−2.3	−1.1	2.8
Middle Atlantic	205	−2.2	−0.3	3.7
South Atlantic	489	−2.2	0.1	4.1
East North Central	907	−2.2	−0.9	3.1
East South Central	491	−2.2	−0.8	3.2
West North Central	1,011	−2.2	−0.9	3.1
West South Central	738	−2.2	−0.5	3.5
Mountain	199	−2.3	−0.6	3.3
Pacific	91	−2.3	−2.0	1.9
Outlying	1	−2.3	0.0	3.9
Ownership				
For profit	10,912	−2.3	0.0	4.0
Non-profit	3,573	−2.3	0.0	3.9
Government	1,018	−2.3	−0.4	3.6

Note: The Total column includes the FY 2024 6.4 percent market basket update. The values presented in Table 30 may not sum due to rounding.

5. Impacts for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) for FY 2025 Through FY 2026

Estimated impacts for the SNF QRP are based on analysis discussed in section VII.C. of this final rule. In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2 percentage points the annual payment update applicable to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year.

As discussed in section VII.C.1.a. of this final rule, we proposed to modify one measure in the SNF QRP beginning with the FY 2025 SNF QRP, the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP COVID–19 Vaccine) measure. We believe that the burden associated with the SNF QRP is the time and effort associated with complying with the non-claims-based measures requirements of the SNF QRP. The burden associated with the HCP COVID–19 Vaccine measure is accounted for under the CDC PRA package currently approved under OMB control number 0938–1317 (expiration January 31, 2024).

As discussed in section VII.C.1.b. of this final rule, we proposed that SNFs would collect data on one new quality measure, the Discharge Function Score (DC Function) measure, beginning with resident assessments completed on October 1, 2023. However, the DC Function measure utilizes data items that SNFs already report to CMS for payment and quality reporting purposes, and therefore, the burden is accounted for in the PRA package approved under OMB control number 0938–1140 (expiration November 30, 2025).

As discussed in section VII.C.1.c. of this final rule, we proposed to remove a measure from the SNF QRP, the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan) measure, beginning with admission assessments completed on October 1, 2023. Although the proposed decrease in burden will be accounted for in a revised information collection request under OMB control number (0938–1140), we are providing impact information.

With 2,406,401 admissions from 15,471 SNFs annually, we estimated an annual burden decrease of 12,032 fewer hours (2,406,401 admissions × 0.005 hr) and a decrease of $1,037,261 (12,038 hrs × $86.2085/hr). For each SNF we estimate an annual burden decrease of 0.78 hours [(12,032 hrs/15,471 SNFs) at a savings of $67.05 ($1,037,261 total burden/15,471 SNFs).

As discussed in section VII.C.1.d. of this final rule, we proposed to remove two measures from the SNF QRP, the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Self-Care Score) and Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (Change in Mobility Score) measures, beginning with assessments completed on October 1, 2023. However, the data items used

in the calculation of the Change in Self-Care Score and Change in Mobility Score measures are used for other payment and quality reporting purposes, and therefore there is no change in burden associated with this proposal.

As discussed in section VII.C.3.a. of this final rule, we proposed to add a second measure to the SNF QRP, the COVID–19 Vaccine: Percent of Patients/Residents Who are Up to Date (Patient/Resident COVID–19 Vaccine) measure, which would result in an increase of 0.005 hours of clinical staff time beginning with discharge assessments completed on October 1, 2024. Although the increase in burden will be accounted for in a revised information collection request under OMB control number (0938–1140), we provided impact information. With 2,406,401 discharges from 15,471 SNFs annually, we estimate an annual burden increase of 12,032 hours (2,406,401 discharges × 0.005 hr) and an increase of $778,5914 (12,032 hrs × $64.71/hr). For each SNF we estimate an annual burden increase of 0.78 hours (12,032 hrs/15,471 SNFs) at an additional cost of $50.33 ($778,591 total burden/15,471 SNFs).

We also proposed in section VII.F.5. of this final rule that SNFs would begin reporting 100 percent of the required quality measures data and standardized patient assessment data collected using the MDS on at least 90 percent of the assessments they submit through the CMS designated submission system beginning January 1, 2024. As discussed in section IX.B.1. of this final rule, this change will not affect the information collection burden for the SNF QRP.

TABLE 31—ESTIMATED SNF QRP PROGRAM IMPACTS FOR FY 2025 THROUGH FY 2027

Total benefit for the FY2025 SNF QRP	Per SNF		All SNFs	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Decrease in burden from the removal of the Functional Assessment/Care Plan measure	(0.78)	($67)	(12,032)	($1,037,261)
Total burden for the FY2026 SNF QRP				
Increase in burden for the Patient/Resident COVID–19 Vaccine measure	0.78	$50	12,032	$778,591

We solicited public comments on the overall impact of the SNF QRP proposals for FY 2025 and 2026.

We did not receive public comments on this provision and therefore, we are finalizing as proposed.

6. Impacts for the SNF VBP Program

The estimated impacts of the FY 2024 SNF VBP Program are based on historical data and appear in Table 32. We modeled SNF performance in the Program using SNFRM data from FY 2019 as the baseline period and FY 2021 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621).

For the FY 2024 program year, we will award each participating SNF 60 percent of their 2 percent withhold. Additionally, in the FY 2023 SNF PPS final rule (87 FR 47585 through 47587), we finalized our proposal to apply a case minimum requirement for the SNFRM. As a result of these provisions, SNFs that do not meet the case minimum specified for the SNFRM for the FY 2024 program year will be excluded from the Program and will receive their adjusted Federal per diem rate for that fiscal year. As previously finalized, this policy will maintain the overall payback percentage at 60 percent for the FY 2024 program year. Based on the 60 percent payback percentage, we estimated that we would redistribute approximately $277.27 million (of the estimated $462.12 million in withheld funds) in value-based incentive payments to SNFs in FY 2024, which means that the SNF VBP Program is estimated to result in approximately $184.85 million in savings to the Medicare Program in FY 2024.

Our detailed analysis of the impacts of the FY 2024 SNF VBP Program is shown in Table 32.

TABLE 32—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2024

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean performance score	Mean incentive payment multiplier	Percent of total payment
Group:					
Total *	11,176	20.47	28.3029	0.99140	100.00
Urban	8,710	20.58	27.1026	0.99084	87.12
Rural	2,436	20.07	32.7202	0.99346	12.88
Hospital-based urban **	196	19.92	36.8240	0.99531	1.72
Freestanding urban **	8,501	20.60	26.8949	0.99074	85.38
Hospital-based rural **	87	19.58	39.2697	0.99636	0.36
Freestanding rural **	2,275	20.08	32.6780	0.99347	12.38
Urban by region:					
New England	627	20.62	27.4602	0.99121	5.45
Middle Atlantic	1,287	20.35	30.2740	0.99220	18.03
South Atlantic	1,691	20.83	25.4855	0.99011	17.75
East North Central	1,593	20.88	22.3914	0.98856	12.69
East South Central	468	20.83	24.1778	0.98938	3.55
West North Central	620	20.24	29.7294	0.99207	3.87

TABLE 32—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2024—Continued

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean performance score	Mean incentive payment multiplier	Percent of total payment
West South Central	912	21.11	18.7872	0.98700	6.75
Mountain	384	19.95	34.9771	0.99429	3.79
Pacific	1,125	19.93	36.2085	0.99528	15.24
Outlying	3	20.46	23.6945	0.98431	0.00
Rural by region:					
New England	75	19.51	40.6317	0.99752	0.55
Middle Atlantic	164	19.56	39.1621	0.99692	0.91
South Atlantic	340	20.37	29.6459	0.99162	2.06
East North Central	602	19.94	33.4406	0.99376	3.07
East South Central	383	20.48	28.5196	0.99167	2.14
West North Central	364	19.81	34.7097	0.99451	1.29
West South Central	345	20.74	24.3765	0.98937	1.68
Mountain	92	19.34	42.4305	0.99792	0.53
Pacific	71	18.48	58.5164	1.00597	0.64
Outlying	0	.....	.....	.....	.....
Ownership:					
Government	464	19.98	34.5948	0.99435	2.86
Profit	8,101	20.60	26.4146	0.99049	75.05
Non-Profit	2,581	20.16	33.2172	0.99378	22.08

* The total group category excludes 3,721 SNFs that failed to meet the finalized measure minimum policy. The total group category includes 30 SNFs that did not have facility characteristics in the CMS Provider of Services (POS) file or historical payment data used for this analysis.

** The group category which includes hospital-based/freestanding by urban/rural excludes 87 swing bed SNFs that satisfied the current measure minimum policy.

In section VIII.B.4.b. of this final rule, we are adopting one additional measure (Nursing Staff Turnover measure) beginning with the FY 2026 program year. Additionally, in section VIII.E.2.b. of this final rule, we are adopting a case minimum requirement for the Nursing Staff Turnover measure. In section VIII.E.2.c. of this final rule, we are maintaining the previously finalized measure minimum for FY 2026. Therefore, we provided estimated impacts of the FY 2026 SNF VBP Program, which are based on historical data and appear in Tables 33 and 34. We modeled SNF performance in the Program using measure data from FY 2019 as the baseline period and FY 2021 as the performance period for the SNFRM, SNF HAI, Total Nurse Staffing, and Nursing Staff Turnover measures. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent. Based on the 60 percent payback percentage, we estimated that we will redistribute approximately $294.75 million (of the estimated $491.24 million in withheld funds) in value-based incentive payments to SNFs in FY 2026, which means that the SNF VBP Program is estimated to result in approximately $196.50 million in savings to the Medicare Program in FY 2026.

Our detailed analysis of the impacts of the FY 2026 SNF VBP Program is shown in Tables 33 and 34.

TABLE 33—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2026

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean total nursing hours per resident day (total nurse staffing)	Mean risk-standardized rate of hospital-acquired infections (SNF HAI) (%)	Mean total nursing staff turnover rate (nursing staff turnover) (%)
Group:					
Total *	13,879	20.39	3.91	7.67	52.74
Urban	10,266	20.52	3.93	7.69	52.43
Rural	3,613	20.04	3.87	7.61	53.62
Hospital-based urban **	239	20.01	5.22	6.52	45.90
Freestanding urban **	10,018	20.53	3.90	7.72	52.57
Hospital-based rural **	143	19.75	4.82	6.88	45.57
Freestanding rural **	3,399	20.04	3.83	7.68	53.93
Urban by region:					
New England	706	20.54	4.04	7.09	45.50
Middle Atlantic	1,408	20.31	3.68	7.55	46.06
South Atlantic	1,810	20.77	4.01	7.86	51.79
East North Central	1,956	20.74	3.59	7.72	55.47
East South Central	538	20.73	3.96	8.02	55.78
West North Central	839	20.18	4.19	7.41	57.73
West South Central	1,207	20.97	3.74	8.02	59.10
Mountain	490	19.94	4.15	7.15	56.54
Pacific	1,309	19.98	4.45	7.84	46.97

TABLE 33—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2026—Continued

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean total nursing hours per resident day (total nurse staffing)	Mean risk-standardized rate of hospital-acquired infections (SNF HAI) (%)	Mean total nursing staff turnover rate (nursing staff turnover) (%)
Outlying	3	20.46	3.30	6.20	N/A
Rural by region:					
New England	106	19.55	4.30	6.63	54.74
Middle Atlantic	192	19.60	3.42	7.17	53.04
South Atlantic	432	20.24	3.72	7.79	52.83
East North Central	802	19.94	3.63	7.46	53.02
East South Central	451	20.43	3.93	8.18	51.90
West North Central	802	19.85	4.12	7.50	53.49
West South Central	577	20.58	3.82	7.99	55.76
Mountain	168	19.54	4.18	7.16	55.96
Pacific	83	18.64	4.34	6.73	53.75
Outlying	0	-	-	-	-
Ownership:					
Government	735	20.00	4.34	7.36	48.93
Profit	9,975	20.51	3.72	7.89	54.29
Non-Profit	3,169	20.11	4.43	7.04	48.74

* The total group category excludes 1,028 SNFs that failed to meet the finalized measure minimum policy.
** The group category that includes hospital-based/freestanding by urban/rural excludes 80 swing bed SNFs that satisfied the finalized measure minimum policy.
N/A = Not available because no facilities in this group received a measure result.

TABLE 34—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2026

Characteristic	Number of facilities	Mean performance score	Mean incentive payment multiplier	Percent of total payment
Group:				
Total *	13,879	24.5877	0.99108	100.00
Urban	10,266	24.4964	0.99106	85.88
Rural	3,613	24.8470	0.99112	14.12
Hospital-based urban **	239	40.2184	1.00671	1.60
Freestanding urban **	10,018	24.1217	0.99069	84.26
Hospital-based rural **	143	41.0606	1.00583	0.38
Freestanding rural **	3,399	24.0807	0.99041	13.62
Urban by region:				
New England	706	30.1328	0.99463	5.31
Middle Atlantic	1,408	26.0014	0.99182	17.27
South Atlantic	1,810	24.1128	0.99014	17.07
East North Central	1,956	18.8610	0.98737	12.69
East South Central	538	21.3335	0.98858	3.49
West North Central	839	26.4267	0.99302	3.99
West South Central	1,207	16.8688	0.98557	7.20
Mountain	490	27.4320	0.99295	3.81
Pacific	1,309	34.7925	0.99925	15.02
Outlying	3	21.6999	0.98682	0.00
Rural by region:				
New England	106	33.4096	0.99729	0.59
Middle Atlantic	192	22.9268	0.98939	0.91
South Atlantic	432	21.3377	0.98797	2.10
East North Central	802	22.3282	0.98960	3.20
East South Central	451	24.1187	0.99020	2.17
West North Central	802	29.2268	0.99485	1.80
West South Central	577	21.1394	0.98792	2.10
Mountain	168	30.0191	0.99532	0.63
Pacific	83	37.8989	1.00119	0.62
Outlying	0	-	-	0.00
Ownership:				
Government	735	33.4591	0.99976	3.20
Profit	9,975	21.0738	0.98806	75.04
Non-Profit	3,169	33.5907	0.99856	21.76

* The total group category excludes 1,028 SNFs that failed to meet the finalized measure minimum policy.
** The group category that includes hospital-based/freestanding by urban/rural excludes 80 swing bed SNFs that satisfied the finalized measure minimum policy.
N/A = Not available because no facilities in this group received a measure result.

In section VIII.B.4. of this final rule, we are adopting three additional measures (Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures) beginning with the FY 2027 program year. Additionally, in section VIII.E.2.b. of this final rule, we are adopting case minimum requirements for the Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures. In section VIII.E.2.d. of this final rule, we are also finalizing an update to our previously finalized measure minimum for the FY 2027 program year. Therefore, we provided estimated impacts of the FY 2027 SNF VBP Program, which are based on historical data and appear in Tables 35 and 36. We modeled SNF performance in the Program using measure data from FY 2019 (SNFRM, SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and DC Function measures), CY 2019 (Long Stay Hospitalization measure), and FY 2018 through FY 2019 (DTC PAC SNF measure) as the baseline period and FY 2021 (SNFRM, SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and DC Function measures), CY 2021 (Long Stay Hospitalization measure), and FY 2020 through FY 2021 (DTC PAC SNF measure) as the performance period. Additionally, we modeled a logistic exchange function with an approximate payback percentage of 66.02 percent for the Health Equity Adjustment, as we finalized in section VIII.E.4.e. of this final rule. Based on the increase in payback percentage, we estimated that we will redistribute approximately $324.18 million (of the estimated $491.03 million in withheld funds) in value-based incentive payments to SNFs in FY 2027, which means that the SNF VBP Program is estimated to result in approximately $166.86 million in savings to the Medicare Program in FY 2027. Of the $324.18 million, $29.56 million is due to the Health Equity Adjustment, as indicated in Table 23 in section VIII.E.4.e. of this final rule.

Our detailed analysis of the impacts of the FY 2027 SNF VBP Program is shown in Tables 35 and 36.

TABLE 35—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2027

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean case-mix adjusted total nursing hours per resident day (total nurse staffing)	Mean risk-standardized hospital-acquired infection rate (SNF HAI) (%)	Mean total nursing staff turnover rate (nursing staff turnover) (%)	Mean risk-standardized discharge to community rate (DTC PAC) (%)	Mean number of risk-adjusted hospitalizations per 1,000 long-stay resident days (long stay hospitalization) (Hosp. per 1,000)	Mean percentage of stays meeting or exceeding expected discharge function score (DC Function) (%)	Mean percentage of stays with a fall with major injury (falls with major injury (long-stay)) (%)
Group:									
Total *	13,672	20.39	3.92	7.68	52.64	51.28	1.47	51.96	3.36
Urban	10,083	20.52	3.94	7.69	52.30	52.03	1.50	51.72	3.07
Rural	3,589	20.03	3.86	7.63	53.58	49.18	1.39	52.61	4.16
Hospital-based urban **	227	20.00	5.26	6.47	46.33	60.97	1.10	46.90	2.17
Freestanding urban **	9,852	20.53	3.91	7.72	52.42	51.82	1.51	51.84	3.09
Hospital-based rural **	138	19.72	4.84	6.86	45.96	52.78	1.07	49.82	4.22
Freestanding rural **	3,409	20.04	3.82	7.68	53.87	48.80	1.40	52.85	4.16
Urban by region:									
New England	706	20.54	4.05	7.09	45.51	55.47	1.41	56.04	3.67
Middle Atlantic	1,397	20.31	3.67	7.56	45.98	49.63	1.40	54.87	2.95
South Atlantic	1,805	20.76	4.02	7.86	51.79	52.38	1.52	50.96	3.10
East North Central	1,871	20.76	3.62	7.72	55.11	52.56	1.52	48.29	3.23
East South Central	533	20.75	3.97	8.04	55.79	50.89	1.49	48.03	3.37
West North Central	827	20.17	4.19	7.41	57.62	51.24	1.51	55.00	3.82
West South Central	1,183	20.98	3.74	8.03	58.96	49.37	1.73	52.38	3.24
Mountain	472	19.93	4.16	7.13	56.75	57.52	1.17	55.02	2.96
Pacific	1,286	19.97	4.44	7.84	47.08	52.86	1.52	49.62	1.89
Outlying	3	20.46	3.30	6.20	N/A	66.54	N/A	50.77	0.00
Rural by region:									
New England	108	19.54	4.32	6.65	54.60	53.27	1.04	57.92	4.18
Middle Atlantic	191	19.57	3.41	7.13	52.89	47.82	1.13	53.15	3.99
South Atlantic	421	20.24	3.73	7.79	52.89	48.10	1.42	49.41	3.84
East North Central	799	19.94	3.63	7.47	52.80	51.48	1.30	49.59	4.14
East South Central	439	20.42	3.92	8.25	51.98	48.11	1.57	48.57	3.65
West North Central	800	19.84	4.10	7.51	53.61	47.74	1.35	56.70	4.77
West South Central	577	20.55	3.82	8.02	55.64	47.69	1.73	53.31	4.17
Mountain	173	19.55	4.17	7.16	55.65	51.94	1.02	58.19	4.22
Pacific	81	18.63	4.32	6.76	54.33	54.64	0.96	55.69	3.11
Outlying:	0	.....	.....	.....	.....	.....	.....	.....	.....
Rural by region:									
Government	717	19.96	4.34	7.38	49.01	50.37	1.41	51.75	3.80
Profit	9,825	20.52	3.73	7.90	54.16	50.32	1.53	51.24	3.17
Non-Profit	3,130	20.10	4.44	7.04	48.71	54.49	1.33	54.25	3.85

* The total group category excludes 1,235 SNFs that failed to meet the finalized four out of eight measure minimum policy.
** The group category that includes hospital-based/freestanding by urban/rural excludes 46 swing bed SNFs that satisfied the finalized measure minimum policy.
N/A = Not available because no facilities in this group received a measure result.

TABLE 36—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2027

Characteristic	Number of facilities	Mean health equity bonus points ***	Mean performance score ****	Mean incentive payment multiplier	Percent of total payment
Group:					
Total *	13,672	1.3922	32.9455	0.99185	100.00
Urban	10,083	1.4065	33.2266	0.99208	85.82
Rural	3,589	1.3522	32.1558	0.99119	14.18
Hospital-based urban **	227	1.0527	45.8943	1.00332	1.59
Freestanding urban **	9,852	1.4151	32.9329	0.99182	84.23
Hospital-based rural **	138	1.0851	43.4161	1.00072	0.38
Freestanding rural **	3,409	1.3752	31.5523	0.99069	13.70
Urban by region:					
New England	706	1.6512	37.2281	0.99477	5.32
Middle Atlantic	1,397	1.5283	34.0874	0.99249	17.29
South Atlantic	1,805	1.2317	32.5500	0.99129	17.10
East North Central	1,871	0.9931	28.9562	0.98911	12.59
East South Central	533	0.9183	29.0674	0.98909	3.49
West North Central	827	0.7315	32.7553	0.99175	3.98
West South Central	1,183	1.3010	27.3676	0.98777	7.18
Mountain	472	1.0725	39.2626	0.99648	3.82
Pacific	1,286	2.8460	42.4505	0.99940	15.04
Outlying	3	0.0000	36.5564	0.99256	0.00
Rural by region:					
New England	108	1.9869	42.3485	0.99953	0.61
Middle Atlantic	191	1.7348	31.4130	0.99020	0.91
South Atlantic	421	1.6187	29.0528	0.98846	2.09
East North Central	799	1.1916	31.2626	0.99059	3.22
East South Central	439	1.6169	29.8730	0.98945	2.16
West North Central	800	0.6760	33.9294	0.99251	1.81
West South Central	577	1.7368	29.1213	0.98892	2.12
Mountain	173	1.3443	39.8837	0.99746	0.64
Pacific	81	2.3226	45.2226	1.00188	0.62
Outlying	0	.....	.....	.....	0.00
Ownership:					
Government	717	1.5059	37.5369	0.99586	3.17
Profit	9,825	1.5991	30.8612	0.99018	75.10
Non-Profit	3,130	0.7168	38.4361	0.99618	21.72

* The total group category excludes 1,235 SNFs that failed to meet the finalized four out of eight measure minimum policy.
** The group category that includes hospital-based/freestanding by urban/rural excludes 46 swing bed SNFs that satisfied the finalized measure minimum policy.
*** Because performance scores are capped at 100 points, SNFs may not receive all health equity bonus points they earn.
**** The mean total performance score is calculated by adding the finalized Health Equity Adjustment bonus points to the normalized sum of individual measure scores. N/A = Not available because no facilities in this group received a measure result.

In section VIII.B.3. of this final rule, we are replacing the SNFRM with the SNF WS PPR measure beginning with the FY 2028 program year. Additionally, in section VIII.E.2.b. of this final rule, we are adopting a case minimum requirement for the SNF WS PPR measure. Therefore, we provided estimated impacts of the FY 2028 SNF VBP Program, which are based on historical data and appear in Tables 37 and 38. We modeled SNF performance in the Program using measure data from FY 2019 (SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and DC Function measures), CY 2019 (Long Stay Hospitalization measure), FY 2018 through FY 2019 (DTC PAC SNF measure), and FY 2019 through FY 2020 (SNF WS PPR measure) as the baseline period and FY 2021 (SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, Falls with Major Injury (Long-Stay), and DC Function measures), CY 2021 (Long Stay Hospitalization measure), FY 2020 through FY 2021 (DTC PAC SNF measure), and FY 2020 through FY 2021 (SNF WS PPR measure) as the performance period. Additionally, we modeled a logistic exchange function with an approximate payback percentage of 65.4 percent, as we finalized in section VIII.E.4.e. of this final rule. Based on the increase in payback percentage, we estimated that we will redistribute approximately $323.23 million (of the estimated $494.21 million in withheld funds) in value-based incentive payments to SNFs in FY 2028, which means that the SNF VBP Program is estimated to result in approximately $170.98 million in savings to the Medicare Program in FY 2028.

Our detailed analysis of the impacts of the FY 2028 SNF VBP Program is shown in Tables 37 and 38.

TABLE 37—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2028

Characteristic	Number of facilities	Mean SNF within-stay potentially preventable readmission rate (SNF WS PPR) (%)	Mean total nursing hours per resident day (total nurse staffing)	Mean risk-standardized hospital-acquired infection rate (SNF HAI) (%)	Mean total nursing staff turnover rate (nursing staff turnover) (%)	Mean risk-standardized discharge to community rate (DTC PAC) (%)	Mean number of risk-adjusted hospitalizations per 1,000 long-stay resident days (long stay hospitalization) (hosp. per 1,000)	Mean percentage of stays meeting or exceeding expected discharge function score (DC Function) (%)	Mean percentage of stays with a fall with major injury (falls with major injury (long-stay)) (%)
Group:									
Total *	14,048	11.57	3.92	7.67	52.74	51.18	1.47	51.96	3.36
Urban	10,313	11.71	3.94	7.69	52.41	51.94	1.51	51.75	3.07
Rural	3,735	11.18	3.87	7.62	53.66	49.10	1.39	52.53	4.15
Hospital-based urban **	230	9.07	5.26	6.48	46.22	60.88	1.10	46.91	2.27
Freestanding urban **	10,079	11.77	3.91	7.72	52.53	51.73	1.51	51.87	3.09
Hospital-based rural **	142	9.44	4.84	6.88	45.96	52.54	1.06	49.90	4.19
Freestanding rural **	3,548	11.30	3.83	7.67	53.95	48.71	1.40	52.75	4.14
Urban by region:									
New England	712	10.70	4.05	7.09	45.49	55.47	1.41	55.98	3.67
Middle Atlantic	1,411	11.66	3.67	7.56	46.02	49.60	1.40	54.80	2.95
South Atlantic	1,827	11.86	4.04	7.85	51.78	52.34	1.53	51.03	3.11
East North Central	1,935	11.88	3.61	7.73	55.28	52.39	1.52	48.33	3.22
East South Central	539	11.77	3.96	8.03	55.87	50.88	1.49	48.20	3.34
West North Central	858	11.27	4.17	7.41	57.92	51.11	1.51	55.12	3.83
West South Central	1,235	12.75	3.73	8.02	59.06	49.27	1.73	52.68	3.21
Mountain	482	10.17	4.17	7.14	56.57	57.32	1.17	54.76	2.98
Pacific	1,310	11.70	4.45	7.84	47.13	52.81	1.53	49.52	1.90
Outlying	4	8.14	4.70	6.52	N/A	64.89	N/A	47.36	0.00
Rural by region:									
New England	112	9.98	4.33	6.67	54.86	52.92	1.05	57.56	4.20
Middle Atlantic	195	10.38	3.41	7.16	53.05	47.85	1.14	52.95	3.94
South Atlantic	436	11.43	3.72	7.76	53.00	48.14	1.42	49.32	3.79
East North Central	824	10.90	3.63	7.48	53.03	51.45	1.30	49.40	4.12
East South Central	451	12.06	3.93	8.23	51.93	48.13	1.57	48.54	3.64
West North Central	854	10.77	4.12	7.50	53.54	47.56	1.34	56.37	4.72
West South Central	603	12.40	3.83	8.02	55.74	47.62	1.72	53.46	4.16
Mountain	178	10.02	4.17	7.15	55.81	51.79	1.03	58.21	4.25
Pacific	82	9.32	4.37	6.76	54.33	54.46	0.97	56.23	3.12
Outlying	0	.....	.....	.....	.....	.....	.....	.....	.....
Ownership:									
Government	737	10.84	4.36	7.38	48.97	50.33	1.42	51.79	3.85
Profit	10,119	11.98	3.72	7.90	54.28	50.25	1.52	51.27	3.17
Non-Profit	3,192	10.45	4.45	7.04	48.74	54.35	1.32	54.19	3.85

* The total group category excludes 859 SNFs that failed to meet the finalized four of eight measure minimum policy.
** The group category that includes hospital-based/freestanding by urban/rural excludes 49 swing bed SNFs that satisfied the finalized measure minimum policy.
N/A = Not available because no facilities in this group received a measure result.

TABLE 38—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2028

Characteristic	Number of facilities	Mean health equity bonus points ***	Mean performance score ****	Mean incentive payment multiplier	Percent of total payment
Group:					
Total *	14,048	1.3866	33.7117	0.99216	100.00
Urban	10,313	1.3834	33.8699	0.99229	85.72
Rural	3,735	1.3952	33.2749	0.99180	14.28
Hospital-based urban **	230	1.0999	50.6699	1.00718	1.59
Freestanding urban **	10,079	1.3903	33.4786	0.99194	84.13
Hospital-based rural **	142	1.1789	46.3840	1.00274	0.38
Freestanding rural **	3,548	1.4162	32.4459	0.99108	13.80
Urban by region:					
New England	712	1.6450	38.8562	0.99580	5.30
Middle Atlantic	1,411	1.4441	34.5592	0.99248	17.19
South Atlantic	1,827	1.2259	33.1678	0.99158	17.04
East North Central	1,935	1.0242	29.8652	0.98953	12.61
East South Central	539	0.9089	30.1968	0.98983	3.48
West North Central	858	0.7433	33.4543	0.99206	4.01
West South Central	1,235	1.2998	28.0800	0.98804	7.28
Mountain	482	1.1398	41.1899	0.99784	3.83
Pacific	1,310	2.7134	41.8142	0.99832	14.99
Outlying	4	0.0000	49.0903	1.00665	0.00
Rural by region:					
New England	112	2.1095	43.5189	1.00029	0.61
Middle Atlantic	195	1.6914	32.6276	0.99092	0.91
South Atlantic	436	1.6562	30.1287	0.98926	2.10
East North Central	824	1.2515	32.2562	0.99102	3.24
East South Central	451	1.6207	30.7335	0.99007	2.16
West North Central	854	0.7418	35.6622	0.99352	1.85
West South Central	603	1.7832	29.8043	0.98910	2.14
Mountain	178	1.4983	41.1638	0.99796	0.64
Pacific	82	2.2569	45.2986	1.00159	0.62
Outlying	0	.....	.....	.....	0.00
Ownership:					
Government	737	1.5601	38.6989	0.99642	3.18
Profit	10,119	1.5762	31.3261	0.99022	75.13
Non-Profit	3,192	0.7454	40.1229	0.99730	21.69

* The total group category excludes 859 SNFs that failed to meet the finalized four out of eight measure minimum policy.
** The group category that includes hospital-based/freestanding by urban/rural excludes 49 swing bed SNFs that satisfied the finalized measure minimum policy.
*** Because performance scores are capped at 100 points, SNFs may not receive all health equity bonus points they earn.
**** The mean total performance score is calculated by adding the finalized Health Equity Adjustment bonus points to the normalized sum of individual measure scores.
N/A = Not available because no facilities in this group received a measure result.

7. Impacts for Civil Money Penalties (CMP): Waiver Process Changes

Current requirements at § 488.436(a) set forth a process for submitting a written waiver of a hearing to appeal deficiencies that lead to the imposition of a CMP which, when properly filed, results in the reduction by CMS or the State of a facility's CMP by 35 percent, as long as the CMP has not also been reduced by 50 percent under § 488.438. We proposed to restructure the waiver process by establishing a constructive waiver at § 488.436(a) that would operate only when CMS has not received a timely request for a hearing. Since a large majority of facilities facing CMPs typically submit the currently required written waiver, this change to provide for a constructive waiver (after the 60-day timeframe in which to file an appeal following notice of CMP imposition) will reduce the costs and paperwork burden for CMS and will also ease the administrative burden for CMS in processing these waiver requests.

This provision will generate operational efficiencies and savings by reallocating staff resources from current responsibilities of tracking and managing the receipt of documentation from facilities requesting a waiver in writing (accounting for approximately one hour per CMP case). For example, in CY 2022, we imposed a total of 11,475 CMPs on 5,319 facilities, with an average of 2.16 CMPs per facility, resulting in a total of 9,191 hours each year (0.80 hours per CMP × 5,319 facilities × 2.16 CMPs per facility) to manage the waiver-related review and processing. In CY 2022, 81 percent (4,308) of the 5,319 facilities with imposed CMPs submitted written waivers. If a constructive waiver were introduced, we estimate that CMS would save roughly $625,315 per year ($84.00 per hour × 7,444 hours per year). Our estimate on the average rate of $84.00 per hour is based on a GS–12, step 5 salary rate of $42.00 per hour, with 100 percent benefits and an overhead package.

Although our focus is on the prioritization of CMS resources for oversight and enforcement activities, finalizing this proposal will also ease the administrative burden for facilities that are currently submitting waiver requests to CMS locations. In CY 2022, 81 percent of facilities facing CMPs filed a waiver; while only 2 percent of facilities filed an appeal of their CMP with the Departmental Appeals Board. The remaining 17 percent of facilities neither waived nor timely filed an appeal. We estimate that moving to a constructive waiver process would

eliminate the time and paperwork necessary to complete and send in a written waiver and would thereby result, as detailed below, in a total annual savings of $2,299,716 in administrative costs for LTC facilities facing CMPs ($861,678 + $1,438,038 = $2,299,716).

We estimate that, at a minimum, facilities will save the routine cost of preparing and filing a letter (estimated at $200 per letter based on the hourly rate of the employee(s) and the time required to prepare and file the letter) to waive their hearing rights. In CY 2022, there were 5,319 facilities who were imposed CMPs. Roughly 81 percent (4,308) of these facilities filed written waivers, therefore, we estimate an annual savings of $861,678 (4,308 × $200) since such letters would no longer be required to receive a 35 percent penalty reduction when a facility is not appealing the CMP.

In addition, we believe that nationally some 17 percent of facilities fail to submit a waiver even though they had no intention of contesting the penalty and its basis. Under the change to offer a constructive waiver automatically, this 17 percent of facilities will now be eligible for the 35 percent CMP amount cost reduction. We note that in CY 2022, CMS imposed a combined total of $190,967,833 in per day and per instance CMPs, with a median total amount due of $4,545. Since CMS imposed CMPs on 5,319 facilities in CY 2022, we estimate a cost savings for 904 facilities (17 percent of 5,319), the typical 17 percent who fail to submit a timely waiver request. We estimate the annual cost savings for these facilities at $1,438,038 ((35 percent × $4,545) × 904 facilities).

Total annual savings from these reforms to facilities and the Federal government together will therefore be $2,925,031 ($2,299,716 plus $625,315).

8. Alternatives Considered

As described in this section, we estimate that the aggregate impact of the provisions in this final rule will result in an increase of approximately $1.4 billion (4.0 percent) in Part A payments to SNFs in FY 2024. This reflects a $2.2 billion (6.4 percent) increase from the update to the payment rates and a $789 million (2.3 percent) decrease as a result of the second phase of the parity adjustment recalibration, using the formula to multiply the percentage change described in section IV.A.4. of this final rule.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket update, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

With regard to the proposals to modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP COVID–19 Vaccine) measure and to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who are Up to Date (Patient/Resident COVID–19 Vaccine) measure to the SNF QRP Program, the COVID–19 pandemic has exposed the importance of implementing infection prevention strategies, including the promotion of COVID–19 vaccination for healthcare personnel (HCP) and residents. We believe these measures will encourage HCP and residents to be ''up to date'' with the COVID–19 vaccine, in accordance with current recommendations of the Centers for Disease Control and Prevention (CDC), and increase vaccine uptake in HCP and residents resulting in fewer cases, less hospitalizations, and lower mortality associated with the virus. We were unable to identify any alternative methods for collecting the data, and there is still an overwhelming public need to target infection control and related quality improvement activities among SNF providers as well as provide data to patients and caregivers about the rate of COVID–19 vaccination among SNFs' HCP and residents through transparency of data. Therefore, these measures have the potential to generate actionable data on COVID–19 vaccination rates for SNFs.

While we proposed to remove the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan) process measure, we also proposed to adopt the Discharge Function Score (DC Function) measure, which has strong scientific acceptability, and satisfies the requirement that there be at least one cross-setting function measure in the Post-Acute Care QRPs that uses standardized functional assessment data elements from standardized patient assessment instruments. We considered the alternative of delaying the proposal of the DC Function measure, but given its strong scientific acceptability, the fact that it provides an opportunity to replace the current cross-setting process measure with an outcome measure, and uses standardized functional assessment data elements that are already collected, we believe further delay is unwarranted. With regard to the proposal to remove the Application of Functional Assessment/Care Plan, the removal of this measure meets measure removal factors one and six set forth in § 413.360(b)(2), and no longer provides meaningful distinctions in improvements in performance.

The proposal to remove the Change in Self-Care Score and Change in Mobility Score measures meets measure removal factor eight set forth in § 413.360(b)(2), and the costs associated with a measure outweigh the benefits of its use in the program. Therefore, no alternatives were considered.

With regard to the proposal to increase the data completion threshold for the Minimum Data Set (MDS) items, the increased threshold of 100 percent completion of the required data elements on at least 90 percent of assessments submitted, is based on the need for substantially complete records, which allows appropriate analysis of quality measure data for the purposes of updating quality measure specifications. These data are ultimately reported to the public, allowing our beneficiaries to gain a more complete understanding of SNF performance related to these quality metrics, and helping them to make informed healthcare choices. We considered the alternative of not increasing the data completion threshold, but our data suggest that SNFs are already in compliance with or exceeding this proposed threshold, and therefore, no additional burden is anticipated.

With regard to the proposals for the SNF VBP Program, we discussed alternatives considered within those sections. In section VII.E.5. of the proposed rule, we discussed other approaches to incorporating health equity into the Program.

9. Accounting Statement

As required by OMB Circular A–4 (available online at *https://*

obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Tables 39 through 43, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule for FY 2024. Tables 30 and 39 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,503 SNFs in our database. Tables 31 and 40 through 41 provide our best estimate of the additional cost to SNFs to submit the data for the SNF QRP as a result of the policies in this proposed rule. Table 42 provides our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies for this program. Table 43 provides our best estimate of the amount saved by LTC facilities and CMS by removing the requirement to submit a written request and establishing a constructive waiver process instead at § 488.436(a) that will operate by default when CMS has not received notice of a facility's intention to submit a timely request for a hearing.

TABLE 39—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2023 SNF PPS FISCAL YEAR TO THE 2024 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers.	$1.4 billion.*
From Whom To Whom?.	Federal Government to SNF Medicare Providers.

*The net increase of $1.4 billion in transfer payments reflects a 4.0 percent increase, which is the product of the multiplicative formula described in section XII.A.4 of this rule. It reflects the 6.4 percent increase (approximately $2.2 billion) from the SNF market basket update to the payment rates, as well as a negative 2.3 percent decrease (approximately $789 million) from the second phase of the parity adjustment recalibration. Due to rounding and the nature of the multiplicative formula, dollar figures are approximations and may not sum.

TABLE 40—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2025 QRP PROGRAM

Category	Transfers/costs
Savings to SNFs to Submit Data for QRP	($1,037,261)

TABLE 41—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2026 SNF QRP PROGRAM

Category	Transfers/costs
Costs for SNFs to Submit Data for QRP	$778,591

TABLE 42—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2024 SNF VBP PROGRAM

Category	Transfers
Annualized Monetized Transfers.	$277.27 million.*
From Whom To Whom?.	Federal Government to SNF Medicare Providers.

*This estimate does not include the 2 percent reduction to SNFs' Medicare payments (estimated to be $462.12 million) required by statute.

TABLE 43—ACCOUNTING STATEMENT: CIVIL MONEY PENALTIES: WAIVER OF HEARING, REDUCTION OF PENALTY AMOUNT

Category	Transfers/costs
Cost Savings of Constructive Waiver	$2,925,031

*The cost savings of $3 million is expected to occur in the first full year and be an ongoing savings for LTC Facilities and the Federal Government.

10. Conclusion

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2023 (87 FR 47502). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2024 are projected to increase by approximately $1.4 billion, or 4.0 percent, compared with those in FY 2023. We estimate that in FY 2024, SNFs in urban and rural areas would experience, on average, a 4.1 percent increase and 3.3 percent increase, respectively, in estimated payments compared with FY 2023. Providers in the urban Middle Atlantic region would experience the largest estimated increase in payments of approximately 5.3 percent. Providers in the urban Outlying region would experience the smallest estimated increase in payments of 1.6 percent.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $30 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $30 million or less in any 1 year. (For details, see the Small Business Administration's website at *https://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*) In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2023 (87 FR 47502). Based on the above, we estimate that the aggregate impact for FY 2024 will be an increase of $1.4 billion in payments to SNFs, resulting from the SNF market basket update to the payment rates, reduced by the second phase of the parity adjustment recalibration discussed in section IV.C. of this final rule, using the formula described in section XII.A.4. of this rule. While it is projected in Table 30 that all providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2024 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2023 Report to Congress (available at *https://www.medpac.gov/wp-content/uploads/2023/03/Ch7_Mar23_MedPAC_Report_To_Congress_SEC.pdf*), MedPAC states that Medicare covers approximately 10 percent of total patient days in freestanding facilities and 16 percent of facility revenue (March 2023 MedPAC Report to Congress, 207). As indicated in Table 30, the effect on facilities is

projected to be an aggregate positive impact of 4.0 percent for FY 2024. As the overall impact on the industry as a whole, and thus on small entities specifically, meets the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule will have a significant impact on a substantial number of small entities for FY 2024.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This final rule will affect small rural hospitals that: (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2023 (87 FR 47502)), the category of small rural hospitals is included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 30, the effect on facilities for FY 2024 is projected to be an aggregate positive impact of 4.0 percent. As the overall impact on the industry as a whole meets the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will have a significant impact on a substantial number of small rural hospitals for FY 2024.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This final rule will impose no mandates on State, local, or Tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This final rule will have no substantial direct effect on State and local governments, preempt State law, or otherwise have federalism implications.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's final rule will be the number of reviewers of this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we believe that the number of commenters on this year's proposed rule is a fair estimate of the number of reviewers of this year's final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

The mean wage rate for medical and health service manages (SOC 11–9111) in BLS OEWS is $61.53, assuming benefits plus other overhead costs equal 100 percent of wage rate, we estimate that the cost of reviewing this rule is $123.06 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is $492.24 (4 hours × $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $39,871.44 ($460.88 × 81 reviewers).

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 20, 2023.

List of Subjects

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 2. Effective January 1, 2024, amend § 411.15 by:

■ a. Redesignating paragraphs (p)(2)(vi) through (xviii) as (p)(2)(viii) through (xx);

■ b. Adding new paragraphs (p)(2)(vi) and (vii); and

■ c. Revising newly redesignated paragraph (p)(2)(xiv).

The additions and revisions read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(p) * * *

(2) * * *

(vi) Services performed by a marriage and family therapist, as defined in section 1861(lll)(2) of the Act.

(vii) Services performed by a mental health counselor, as defined in section 1861(lll)(4) of the Act.

* * * * *

(xiv) Services described in paragraphs (p)(2)(i) through (viii) of this section when furnished via telehealth under section 1834(m)(4)(C)(ii)(VII) of the Act.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 4. Section 413.338 is amended by—
■ a. Removing the paragraph designations for paragraphs (a)(1) through (17);
■ b. In paragraph (a) adding definitions in alphabetical order for ''Health equity adjustment bonus points'', ''Measure performance scaler'', ''Top tier performing SNF'', ''Underserved multiplier'', and ''Underserved population'';
■ c. Revising paragraphs (c)(2)(i), (d)(4)(v), and (e)(2) introductory text;
■ d. Adding paragraph (e)(3);
■ e. Revising paragraph (j); and
■ f. Adding paragraph (k).

The additions and revisions read as follows:

§ 413.338 Skilled nursing facility value-based purchasing program.

(a) * * *

Health equity adjustment (HEA) bonus points means the points that a SNF can earn for a program year based on its performance and proportion of SNF residents who are members of the underserved population.

* * * * *

Measure performance scaler means, for a program year, the sum of the points assigned to a SNF for each measure on which the SNF is a top tier performing SNF.

* * * * *

Top tier performing SNF means a SNF whose performance on a measure during the applicable program year meets or exceeds the 66.67th percentile of SNF performance on the measure during the same program year.

Underserved multiplier means the mathematical result of applying a logistic function to the number of SNF residents who are members of the underserved population out of the SNF's total Medicare population, as identified from the SNF's Part A claims, during the performance period that applies to the 1-year measures for the applicable program year.

Underserved population means Medicare beneficiaries who are SNF residents in a Medicare Part A stay who are also dually eligible, both partial and full, for Medicaid.

* * * * *

(c) * * *

(2) * * *

(i) *Total amount available for a fiscal year.* The total amount available for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the assignment of a performance score to low-volume SNFs under paragraph (d)(3) of this section. Beginning with the FY 2023 SNF VBP, the total amount available for value-based incentive payments for a fiscal year is 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS. Beginning with the FY 2027 SNF VBP, the total amount available for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the application of the Health equity adjustment bonus points as calculated under paragraph (k) of this section.

* * * * *

(d) * * *

(4) * * *

(v) CMS will calculate a SNF Performance Score for a fiscal year for a SNF for which it has granted an exception request that does not include its performance on a quality measure during the calendar months affected by the extraordinary circumstance.

* * * * *

(e) * * *

(2) *Calculation of the SNF performance score for fiscal year 2026.* The SNF performance score for FY 2026 is calculated as follows:

* * * * *

(3) *Calculation of the SNF performance score beginning with fiscal year 2027.* The SNF performance score for a fiscal year is calculated as follows:

(i) CMS will sum all points awarded to a SNF as described in paragraph (e)(1) of this section for each measure applicable to a fiscal year.

(ii) CMS will normalize the SNF's point total such that the resulting point total is expressed as a number of points earned out of a total of 100.

(iii) CMS will add to the SNF's point total under paragraph (e)(3)(ii) of this section any applicable health equity adjustment bonus points calculated under paragraph (k) of this section such that the resulting point total is the SNF Performance Score for the fiscal year, except that no SNF Performance Score may exceed 100 points.

* * * * *

(j) *Validation.* (1) Beginning with the FY 2023 program year, for the SNFRM measure, and beginning with the FY 2026 program year for all other claims-based measures, the information reported through claims are validated for accuracy by Medicare Administrative Contractors (MACs).

(2) Beginning with the FY 2026 program year, for all measures that are calculated using Payroll-Based Journal System data, information reported through the Payroll-Based Journal system is validated for accuracy by CMS and its contractors through quarterly audits.

(3) Beginning with the FY 2027 program year, for all measures that are calculated using Minimum Data Set (MDS) information, such information is validated for accuracy by CMS and its contractors through periodic audits not to exceed 1,500 SNFs per calendar year.

(k) *Calculation of the Health equity adjustment (HEA) bonus points.* CMS calculates the number of HEA bonus points that are added to a SNF's point total calculated under paragraph (e)(3)(iii) of this section by:

(1) Determining for each measure whether the SNF is a top tier performing SNF and assigning two points to the SNF for each such measure;

(2) Summing the points calculated under paragraph (k)(1) of this section to calculate the measure performance scaler;

(3) Calculating the underserved multiplier for the SNF; and

(4) Multiplying the measure performance scaler calculated under paragraph (k)(2) of this section by the underserved multiplier calculated under paragraph (k)(3) of this section.

■ 5. Section 413.360 is amended by revising paragraphs (f)(1) and (2) to read as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

* * * * *

(f) * * *

(1) SNFs must meet or exceed the following data completeness thresholds with respect to a calendar year:

(i) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the Minimum Data Set (MDS) on at least 80 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2018 through FY 2025 program years.

(ii) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the MDS on at least 90 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2026 and for all subsequent payment updates.

(iii) The threshold set at 100 percent for measures data collected and submitted through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for FY 2023 and for all subsequent payment updates.

(2) These thresholds apply to all measures and standardized patient assessment data requirements adopted into the SNF QRP.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 6. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 7. Section 488.432 is amended by revising paragraph (c) to read as follows:

§ 488.432 Civil money penalties imposed by the State: NF–only.

* * * * *

(c) *When a facility waives a hearing.* (1) If a facility waives its right to a hearing as specified in § 488.436, the State initiates collection of civil money penalty imposed per day of noncompliance after 60 days from the date of the notice imposing the penalty and the State has not received a timely request for a hearing.

(2) If a facility waives its right to a hearing as specified in § 488.436, the State initiates collection of civil money penalty imposed per instance of noncompliance after 60 days from the date of the notice imposing the penalty and the State has not received a timely request for a hearing.

* * * * *

■ 8. Section 488.436 is amended by revising paragraph (a) to read as follows:

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) *Constructive waiver of a hearing.* A facility is considered to have waived its right to a hearing after 60 days from the date of the notice imposing the civil money penalty if CMS has not received a request for a hearing from the facility.

* * * * *

■ 9. Section 488.442 is amended by revising paragraph (a)(2) introductory text to read as follows:

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) * * *

(2) *After the facility waives its right to a hearing in accordance with § 488.436(a).* Except as provided for in § 488.431, a civil money penalty is due 75 days after the notice of the penalty in accordance with § 488.436 and a hearing request was not received when:

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 10. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 11. Effective January 1, 2024, amend § 489.20 by:

■ a. Redesignating paragraphs (s)(6) through (18) as paragraphs (s)(8) through (20), respectively;

■ b. Adding new paragraphs (s)(6) and (7); and

■ c. Revising newly redesignated paragraph (s)(14).

The additions and revisions read as follows:

§ 489.20 Basis commitments.

* * * * *

(s) * * *

(6) Services performed by a marriage and family therapist, as defined in section 1861(lll)(2) of the Act.

(7) Services performed by a mental health counselor, as defined in section 1861(lll)(4) of the Act.

* * * * *

(14) Services described in paragraphs (s)(1) through (8) of this section when furnished via telehealth under section 1834(m)(4)(C)(ii)(VII) of the Act.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–16249 Filed 7–31–23; 4:15 pm]

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